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Critical Issue Report: Reducing Pesticide Dietary Exposure



Successes and Lost Opportunities to Reduce Children's Exposure to Pesticides Since the Mid-1990s

by Charles M. Benbrook

Chief Scientist, The Organic Center

August 2006

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INTRODUCTION AND SUMMARY

I

This “Critical Issues” report synthesizes papers written by the four scientists who made presentations at the 2006 American Association for the Advancement of Science (AAAS) annual meeting symposium entitled “Opportunities and Initiatives to Minimize Children’s Exposures to Pesticides”. The symposium occurred February 16th in St. Louis, Missouri.

Dr. Alan Greene, a pediatrician, served as co-symposium organizer with Dr. Charles Benbrook, and presented the session’s introductory talk. Dr. Greene is chief medical officer of A.D.A.M., a leading publisher of interactive health information. His award-winning website, www.DrGreene.com, is devoted to health information. He is an attending physician at Stanford University’s Lucile Packard Children’s Hospital.

Dr. Chensheng (Alex) Lu, Ph.D., is an assistant professor of environmental and occupational health, Emory University, Atlanta GA. Dr. Lu described the findings of a key dietary intervention study that highlights the impact of diets composed of predominantly organic foods on exposures to a class of high-risk insecticides.

Dr. Charles Benbrook is the Organic Center’s Chief Scientist. He has worked on pest management, pesticide risk, and regulatory issues since 1981. He spent 17 years in Washington, D.C., working for the Executive Office of the President, the U.S. Congress, and the National Academy of Sciences/National Research Council. He was the Executive Director of the NAS/NRC Board on Agriculture during the period when two critical studies on pesticide risk-regulatory issues were carried out. In his AAAS paper, Dr. Benbrook reviews private sector efforts to reduce risks and identifies some clear winners and losers.

Dr. Philip J. Landrigan, a pediatrician, is the director for the Center for Children’s Health and the Environment at the Mount Sinai School of Medicine in New York. From 1995 to 1997, he served on the Presidential Advisory Committee on Gulf War Veteran’s Illnesses. Dr. Landrigan chaired the NAS committee that wrote *Pesticides in the Diets of Infants and Children*, a report that was instrumental in securing passage of the Food Quality Protection Act of 1996. In a paper co-authored by Dr. Benbrook, Dr. Landrigan assesses the impacts of the Food Quality Protection Act after 10 years of implementation, and provides an overall assessment of progress made and challenges ahead in reducing children’s exposures to pesticides.

Significant progress has been made in the past decade in improving the databases and analytical methods available to establish benchmarks for children’s exposures to pesticides and resultant risks. We also have much-improved capability to track trends in exposures and risks.

Risks associated with organophosphate (OP) insecticides were a major focus in the AAAS symposium and are featured in this “Critical Issues” report. This class of insecticides is the most widely used in food production worldwide, poses the most worrisome developmental risks stemming from pesticide use, and has been the dominant focus of the U.S. Environmental Protection Agency (EPA) for more than a decade.

We describe and contrast the effectiveness of four major approaches to reducing pesticide risks:

- Discovery and use of reduced-risk and biologically-based pesticides;
- Adoption of biointensive pest management systems, including organic production methods;
- Marketplace incentives and ecolabels, including organic production; and
- Regulation.

New Chemistry

Several important classes of new pesticides have been developed and adopted over the last decade that are less toxic and persistent, and less likely to find their way into food, drinking water, and the environment. These new chemistries have displaced many uses of higher-risk pesticides and helped achieve significant risk reduction.

Shift to Biointensive Integrated Pest Management

From the 1960s through the 1990s, farmers have relied largely upon pesticides to keep pest populations below economic thresholds. The focus of most pest management specialists was chemical control of populations that threatened farm yields, crop quality, and profits.

Concern over the impacts of DDT on wildlife populations in the 1960s and 1970s, and early experiences with the emergence of pesticide-resistant pest populations, raised questions about the sustainability of pest management systems largely reliant on chemical control. These questions led to early research on Integrated Pest Management (IPM) and biological control.

IPM systems exist along a continuum from largely pesticide-based to fully dependent upon prevention and biological interventions. Successful biointensive IPM requires a shift in the focus of farmers and pest managers to prevention through the management of biological systems, and away from treatments using chemicals (Benbrook et al., 1996). While a significant share of American farmers utilize one or a few core elements of IPM, pesticides remain by far the dominant pest management tool in American agriculture.

A small but growing percentage of farmers are using organic production systems that prohibit the use of toxic synthetic pesticides, and place heavy emphasis on cultural, mechanical and biological control tactics. Organic farmers are allowed to augment their biointensive IPM systems with use of a few dozen, low-risk pesticides that are derived, for the most part, from microbes and natural materials.

Food Marketplace Incentives and Ecolabels

Food companies and grower groups have promoted adoption of IPM and reduced-risk pest management systems through a variety of marketplace initiatives. Most programs include some sort of ecolabel that certifies that food was grown in ways reducing the environmental impacts of farming systems.

Ecolabels making pesticide-related claims typically are based on:

- Presence of “No Detectable [Pesticide] Residues,” or NDR (also sometimes called “pesticide free”);
- Use of Integrated Pest Management (IPM grown); and/or
- Produced in accord with the principles of organic farming (certified organic).

Regulation

Through the 1970s and until the late 1990s, the EPA based its pesticide risk assessments on exposures to healthy adults. The Food Quality Protection Act (FQPA), passed in 1996, directed the EPA to conduct a reassessment of all food uses of pesticides, taking into account the heightened susceptibility of infants and children, the elderly, and other vulnerable population groups.

The summary of the AAAS symposium that follows was issued during the meeting as a joint statement signed by the four presenters. It highlights our key findings and conclusions regarding the effectiveness of efforts in the last decade to reduce children’s exposures to pesticides.

Joint Statement on Pesticides, Infants and Children Issued February 19, 2006, at the AAAS Annual Meeting

We believe that the scientific case supporting the need to significantly reduce prenatal and childhood exposures to pesticides has greatly strengthened over the last decade, since passage of the Food Quality Protection Act (FQPA) in 1996. Evidence of the developmental neurotoxicity of several commonly used pesticides is particularly compelling. The FQPA provided the Environmental Protection Agency (EPA) important new tools, ten years, and a mandate to address these sorts of risks and assure that there is a “reasonable certainty of no harm” from government-approved pesticide uses, with special focus on pregnant women, infants and children.

The EPA has acted decisively to eliminate most residential uses of the organophosphate (OP) insecticides. There is encouraging evidence that actions taken to date on residential pesticide uses are producing public health benefits. Equally decisive steps to reduce dietary exposures to high-risk OP pesticides have been regrettably few and far between. Human biomonitoring data shows that only modest progress has been made in reducing OP exposures since passage of the FQPA.

Strong data point to a dramatic shift of pesticide dietary risks from fresh fruits and vegetables grown in the U.S. to those imported from abroad. As a nation, we have more work to do, and contentious decisions ahead if we are to markedly reduce pesticide dietary risks.

How can we best approach this task? In the last decade, significant public and private resources have been invested with the goal of reducing pesticide risks through:

- The discovery and registration of safer pesticides;
- Adoption of Integrated Pest Management systems;
- Ecolabel programs, including “certified organic;” and
- Regulation.

We conclude that discovery of reduced risk pesticides has significantly facilitated the transition by many farmers away from high-risk pesticides. This transition has clearly helped reduce risks in some key children's foods. EPA policies put in place to expedite registration of reduced risk products should be strengthened.

Adoption of Integrated Pest Management (IPM) has had limited impacts on pesticide use and risks. Most IPM systems are focused on using pesticides efficiently and lack even a secondary focus on dietary risk reduction.

Ecolabel programs have had modest impacts on pesticide risks because they collectively impact so few acres, and many programs do not require farmers to markedly change pest management systems. Organic farming is the clear exception, and offers one proven way to quickly and dramatically reduce children's exposures. Studies led by Dr. Chensheng Lu of Emory University have shown that a predominantly organic diet essentially eliminates evidence of exposure to certain widely used organophosphate insecticides.

Regulation, and the FQPA in particular, has advanced knowledge of pesticide risks and addressed residential risks reasonably well, but has done little to reduce pesticide dietary risks. The FQPA is a fundamentally sound law, but it has not delivered fully on its promise to reduce children's pesticide risks because of the EPA's hesitancy to fully use the law's strong new provisions.

In the absence of more decisive action by EPA, significant near-term reductions in pesticide dietary risks are attainable, but only if farmers are provided support and incentives to change pest management systems, and only if consumers demand change.

We conclude that enhanced efforts by the government and food industry to increase both the supply and demand for organic food will deliver the most significant near-term public health gains, especially if the focus is on expanding consumption of fresh and processed organic fruits and vegetables, while reducing consumption of foods high in added sugar and added fat content. Building such requirements into the school lunch and WIC programs are obvious ways to start.

SCIENCE SUPPORTING THE NEED TO REDUCE CHILDREN'S EXPOSURES TO PESTICIDES



Substantial evidence gathered over the past half century has shown that environmental exposures in early life can alter patterns of childhood development, and influence lifelong health and risk of disease and dysfunction (National Research Council, 1993).

Some chemical exposures identified as potentially harmful to early development include: cigarette smoking during pregnancy (Haddow et al., 1998), lead (Dietrich et al., 2001; Ris et al., 2004), alcohol consumption (Lupton et al., 2004), ionizing radiation (Newcombe et al., 1971), polychlorinated biphenyls (Longnecker et al., 1997) (Jacobson et al., 1996), methyl mercury (Trasande et al., 2005a), outdoor air pollutants (Trasande et al., 2005b), benzene (Pedersen et al., 2004; Raaschou-Nielsen et al., 2001), organochlorine pesticides (Longnecker et al., 1997; Longnecker et al., 2001; Longnecker et al., 2002), and certain other pesticides (Gray et al., 2001), especially the organophosphate (OP) insecticides (NRC, 1993).



Prenatal factors and early childhood exposures also play a role in disease development in later life (Barker 2004a; Barker 2004b; Barker et al., 2005; Barker 2005; Eriksson et al., 2003; Forsen et al., 2004; Kajantie et al., 2005; Syddall et al., 2005). Exposures during fetal growth have been linked to risk of cardiovascular dysfunction, hypertension (high

blood pressure), and diabetes in adulthood. Rapid growth during childhood is related to subsequent risk of breast cancer in women (Ahlgren et al., 2003; Ahlgren et al., 2004), as well as to impaired glucose tolerance in adulthood. There are almost certainly additional etiologic associations -- some subtle but nonetheless important across a large population -- between the environment, pre- and perinatal exposures, and disease in children.

Progress in identifying the environmental causes of disease has been slow and incremental. Reasons include the fact that most studies have:

- Examined relatively small populations of pregnant women and their offspring;
- Focused on one chemical at a time;
- Lacked the statistical power needed to examine interactions among chemical, social, and behavioral factors in the environment, and gene-environment interactions; and
- Suffered from short-lived follow-ups.

Previous discoveries of environmental exposures that influence children's health and development have produced significant gains for disease prevention. Examples include quitting or even simply cutting back on alcohol and tobacco during pregnancy (Lumley et al., 2004), minimization of diagnostic X-rays during pregnancy, and removal of lead from gasoline (Grosse et al., 2002). Evidence is presented in this report suggesting that the major changes in regulation called for in the Food Quality Protection Act (FQPA) have begun to reduce infant and child exposures to OP insecticides, resulting in tangible improvements in reproductive outcomes and children's health.

A. The Changing Patterns of Disease in American Children

Patterns of illness have changed substantially in the past century among children in the United States and other industrial nations (see Centers for Disease Control statistics at <http://www.cdc.gov/nchs/hus.htm>). Infant mortality has declined. Life expectancy has increased. With notable exceptions such as HIV/AIDS, infectious diseases have receded as the leading cause of illness and death.

Today, the major illnesses confronting children in the United States are a group of chronic conditions, including a number of psychosocial and behavioral conditions, termed the "new pediatric morbidity" (Haggerty 1995). These include:

- Asthma: The leading cause of hospitalization and school absenteeism, asthma more than doubled in incidence between 1980 and

- 1996 (Centers for Disease Control, 1998);
- Cancer: The incidence of childhood and young adult cancers, such as acute lymphocytic leukemias, brain tumors and testicular malignancies has increased by 10 percent (Shu et al., 1995), 40 percent (Schechter, 1999) and 68 percent, respectively (Devesa et al., 1995), over the past 15 to 30 years, despite declining mortality;
- Neurodevelopmental disorders: Mental retardation, learning disabilities, attention deficit disorder, and autism affect 5-10 percent of the 4 million children born in the U.S. annually -- that's up to 400,000 cases, more so than previously thought (Bertrand et al., 2001; LeFever et al., 1999); and
- Obesity and type 2 diabetes: These preventable conditions are epidemic among American children. In 2003, 43 percent of children entering kindergarten in New York City were overweight or obese (Thorpe et al., 2004).

Beyond childhood, incidence rates of chronic neurodegenerative diseases of adult life, such as Parkinson's disease and dementia, have increased notably. These trends raise the possibility that exposures in early life act as triggers of later illness, perhaps by diminishing the numbers of brain cells to below the level needed to maintain healthy function in the face of advancing age. Prenatal and childhood exposures to pesticides have emerged as a significant risk factor explaining impacts on brain



structure and health that can increase the risk of neurological disease later in life (Landrigan et al., 2005).

B. The Need to Further Reduce Exposures

During fetal development and the first years of life, infants are much less able to detoxify most pesticides and are uniquely vulnerable to developmental toxins, especially neurotoxins. Heightened vulnerability arises from the ability of pesticides to pass through the blood-brain barrier, and the long period of time during which the brain and nervous system continue to develop (Cooper et al., 1999; Eskenazi et al., 1999; National Research Council, 1993; Shaw et al., 1999; Whyatt et al., 2003; Zahm et al., 1998).

A team of researchers at the University of California-Berkeley School of Public Health found that exposures to pesticides during pregnancy significantly heightened risk of children developing leukemia, and that the more frequent the exposures and the earlier in life, the greater the increase in risk (Ma et al., 2002). A team in the Department of Preventive Medicine, University of Southern California, found that exposure to pesticides in the home during fetal development and the early years of life increased the risk of non-Hodgkin's lymphoma, with odds ratios as high as 9.6 for Burkitt lymphoma (Buckley et al., 2000).

A study involving more than 44,000 children measured pesticide residues in stored frozen blood samples from pregnancies in the early 1960s (Longnecker et al., 2001). Children were divided into five groups based on levels of maternal pesticide exposure. Odds ratios were calculated for preterm birth and small-for-gestational-age babies across the five groups, and increased in a dose-response manner as shown in Table 1. Those in the group with even the smallest exposure had a 50 percent increased chance of being born prematurely, compared to those with none. Those at the highest level had greater than a 200 percent increased chance of premature birth. The authors estimate that pesticide exposure was responsible for 15 percent of all infant deaths during the years of the study, the only such estimate we are aware of.

In June 2005, *Science* published the first study to show that developmental changes triggered by pesticides can last multiple generations (Anway et al., 2005). Fungicides were shown to cause

decreased sperm counts and mobility – not just to animals exposed in utero, but for three subsequent generations. In other words, assuming the same biological impacts occur in humans, what each of us was exposed to in our mother's womb might impact the health of our great-grandchildren – for better or for worse.

A recent study of 110 urban and suburban children found measurable levels of organophosphate (OP) pesticide metabolites in their urine samples -- except for one child, whose parents reported buying exclusively organic produce (Lu et al. 2001). Curl et al. (2001) carried out a more comprehensive study in which two groups of two to five year-old Seattle

Table 1. Maternal serum DDE concentration in relation to odds of perterm or small-for-gestational-age birth

	SERUM DDE (µg/L)				
	<15	15-29	30-44	45-59	> or = 60
PRETERM BIRTH					
Number of cases	34	153	80	50	44
Number of controls	375	944	404	176	120
Adjusted odds ratio (95% CI)	1	1 to 5	1 to 6	2 to 5	3 to 1
SMALL-FOR-GESTATIONAL-AGE					
Number of cases	20	10	47	22	26
Number of controls	389	991	436	204	138
Adjusted odds ratio (95% CI)	1	1 to 9	1 to 7	1 to 6	2 to 6

A study was conducted jointly by investigators at the Center for Research on Women's and Children's Health, the Mount Sinai School of Medicine, the University of North Carolina, Chapel Hill, the Kaiser Permanente Division of Research, and the University of California San Francisco School of Medicine (Cohn et al., 2003). They measured pesticide metabolites in preserved postpartum maternal serum samples from 1960 to 1963. They also recorded time to pregnancy in the subjects' eldest daughters 28-31 years later. The daughters' probability of pregnancy fell by 32 percent for each 10 mcg/L detected, three decades after the exposure.

Scientists in Ontario, Canada, showed that exposures to pesticides three months prior to conception and during pregnancy increased the risk of spontaneous abortions (Arbuckle et al., 2001).

C. Organic Diet Intervention Studies Highlight Opportunities to Reduce Exposures

Recent work has indicated that children's diets may contain pesticides at levels above the acute population-adjusted reference dose (Fenske et al. 2002; EPA cumulative risk assessment of the OPs). This is because 1) Children tend to eat more fruits, juices and even vegetables than adults, relative to body weight; and 2) Children by nature have less-efficient immune and detoxifying systems compared to those of adults.

children were monitored. Parents of one group were selected at the entrance-way of a conventional food store. The second group of parents was identified at an organic food store. The study entailed a comparison of biomarkers of pesticides in the urine of children consuming a predominantly conventional diet, compared to the children eating mostly organic foods.

The conventional group consisted of 21 children, and the organic group totaled 18 children. None of the families reported any recent pesticide use in and around the home. The parents fed their children as they had always done. Food diaries were kept over a three-day period and urine samples were collected. The researchers examined five OP metabolites, each known to be a biomarker for exposure to one or more OP insecticides. The median level of the dimethyl metabolite in the children in the conventional group was six times higher than the median amount detected in the children in the organic food group.

Curl et al. concluded that the results show that eating organic produce can markedly lower children's exposures from possibly above the EPA's current safety guidelines, to negligible risk levels. Feeding kids organic rather than conventional food emerged in this study as a relatively easy way to reduce OP dietary exposures.

The surprising findings in the Curl et al. study triggered much discussion and debate. A larger, more rigorous dietary intervention study was initiated in 2003-2004 by Dr. Chenshung Lu, one of

the Curl team researchers. A cohort of 23 school-age children in the Seattle, Washington area was selected (Lu et al., 2005). The study included three phases of testing for OP insecticide metabolites in urine. The first followed a period when the children consumed their normal diet of conventionally grown foods. Phase 2 testing was carried out five days after the children had switched to predominantly organic sources of the same foods, and the third phase of testing occurred after a return to a conventional diet for five days.

All 23 children had OP insecticide metabolites in their urine in phase 1 testing, while levels were below the limit of detection during phase 2, following the consumption of mostly organic food for just five days. Once the children were back on their typical, conventional food-based diet in phase 3, the levels of insecticide metabolites in urine reverted within days to those found in phase 1.

This carefully designed and conducted study confirmed the findings of the earlier Curl et al. study, and eliminated uncertainty regarding the identification of the OPs leading to specific metabolites in the children's urine. They accomplished this in the second study by only testing for two major OPs with distinct urinary metabolites – malathion and chlorpyrifos. Lu et al. (2006) concluded, however, that their findings on malathion and chlorpyrifos almost certainly apply to other major OPs in the diet. The Lu et al. team's conclusion: An organic diet "...provides a dramatic and immediate protective effect against exposures to OP pesticides."

Dr. Lu is currently conducting a third dietary intervention study, this time involving children in the Atlanta, Georgia, area; results are expected by end of 2006.

TWO MILESTONES



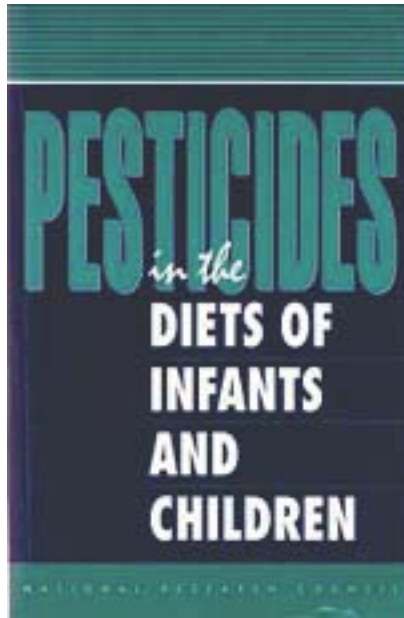
Two milestones in the 1990s solidified scientific and political consensus in the United States around the need for systematic efforts to reduce pesticide exposures and risks during pregnancy, infancy, and childhood.

In 1993, the National Academy of Sciences released the report *Pesticides in the Diets of Infants and Children* (National Research Council, 1993). Dr. Phil Landrigan chaired the National Academy of Sciences/National Research Council (NAS/NRC) Committee that wrote this landmark report; Dr. Charles Benbrook was the Executive Director of the NRC board that issued the report.

After assessing the science base supporting pesticide regulation, the Committee reached several important conclusions:

- Pregnant women, infants, and children face unique and possibly significant developmental and endocrine-system mediated risks from low-level pesticide exposures during critical windows of development, some with serious lifelong consequences;
- Infants and children consume more food per kilogram of bodyweight than adults, and a less varied diet, increasing risks when pesticides are present in a food consumed by children;
- Children are less able to detoxify many chemicals, and rapidly developing organ systems are highly vulnerable during critical stages of development;
- Government risk assessment methods used to determine acceptable residues in foods (governed by tolerances) were not designed to detect nor quantify the majority of these unique risks; and
- Then-current pesticide exposure data and risk assessment models fail to reflect real-world exposures and risks. Deficiencies can only be rectified by carrying out cumulative risk assessments (CRA) across all routes of exposure, encompassing residues of all pesticides that work through a

common mechanism of action (e.g., the organophosphate insecticides, all of which are cholinesterase inhibitors).



Passage of the FQPA was the second milestone in the 1990s (USEPA, 1997). The goal of the FQPA was to assure by 2006 a “reasonable certainty of no harm” as a result of pesticide exposures for all U.S. population groups. The FQPA:

- Established a stricter, health-based standard (as opposed to the previous cost-benefit-balancing standard) for pesticide regulation, with special emphasis on risks facing infants and children, plus pregnant women and the elderly;
- Gave the EPA 10 years to develop new risk assessment tools, and to review and update some 9,600 tolerances covering pesticide residues in food. Deadline for all tolerances to be reviewed and adjusted – August 2006; and
- Provided the EPA important new regulatory tools, and a mandate, to reduce pesticide risks to the above-named vulnerable population groups.

A. Genesis of the FQPA

From the early 1970s through July 1996, the EPA searched for ways to abide by conflicting statutory provisions in the two federal laws governing the establishment, review, and modification of pesticide tolerances.

The Delaney Clause, a provision in Section 409 of the Food, Drug and Cosmetic Act, prohibited government agencies from knowingly approving a food additive that poses any level of cancer risk. The Delaney Clause applied to tolerance setting when pesticide residues became concentrated in processed or dried foods, because concentrated residues were regarded as food additives. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the statute governing pesticide regulation,

called upon the EPA to apply a risk-benefit standard when deciding whether a tolerance could be set covering residues of cancer-causing pesticides, including those known to concentrate in processed food.

To resolve this discrepancy, the EPA in 1984 commissioned a National Academy of Sciences (NAS) review of the conflicting standards and bases for pesticide tolerance setting. This analysis resulted in the 1987 NAS/NRC report *Regulating Pesticides in Food: The Delaney Paradox*. This report called for fundamental changes in federal law and pesticide risk assessment procedures. It also concluded that pregnant women, infants, and children faced unique threats from pesticide exposure, and that existing EPA risk assessment procedures were not taking these unique risks into account (NAS, 1987).

As a follow-up to the “Delaney Paradox” report, the U.S. Congress in 1988 directed the EPA to request an NAS review of pesticides and risks to children. One of the authors of this report (Philip J. Landrigan) was asked to chair the NAS/NRC committee that took on this task. Our committee first met in October of 1988, and our report was released in June 1993 (National Research Council, 1993). The major finding of this report was that children are profoundly different from adults in their exposures

and vulnerability to pesticides. The young are not merely smaller versions of adults. They are rapidly evolving beings, uniquely defenseless to lifelong consequences from ill-timed, short-term, low-level exposures to pesticides. By nature, the growing human body has a diminished capacity to detoxify and excrete many chemical toxins. For these reasons the report called for fundamental revision of the procedures used to establish pesticide tolerances to account for children’s unique susceptibility to pesticides.

The 1993 NAS/NRC report marked the emergence of a new consensus in the public health community that regulation of toxic chemicals must focus, first and foremost, on protecting infants and children. It led to the creation and refinement of the U.S. Department of Agriculture’s “Pesticide Data Program,” and to major new EPA research initiatives. It also helped break a political stalemate that had persisted for 20 years involving reform of the Delaney Clause.

Each year from the mid-1970s through 1996, members of Congress held hearings and introduced legislative proposals calling for either stricter application of the Delaney Clause or its repeal. When the 1993 NAS report was issued, its findings and recommendations for fundamental regulatory reform were well received by the EPA, pesticide industry, and most environmental organizations. The report provided the foundation for a way to unravel the Delaney Paradox and bring modern science to the assessment and regulation of pesticide risks to infants and children.



The high drama over the reform of the Delaney Clause came to an abrupt end on July 24, 1996, when the House of Representatives passed the Food Quality Protection Act (FQPA) without a single dissenting vote after only a few minutes of discussion. On the next day, the Senate passed the bill on a unanimous consent motion after barely one minute of discussion.¹

The *Washington Post* Sunday edition ran a story describing the long process that led to passage of the FQPA. The lead paragraph states:

“The new federal food safety law, which swept through Congress without opposition and was blessed by many industry and environmental groups, is a rare legislative compromise in which all sides can declare a measure of victory.” (Washington Post, July 28, 1996).

¹ For details on the FQPA, its passage, President Clinton’s signing statement and news accounts of the passage of the bill, see <http://www.ecologic-ipm.com/fqpa.html>

In his August 3rd statement at the FQPA-signing ceremony, President Bill Clinton said:

"From the day I took office, I have worked hard to meet what I think is a fundamental promise that we should make to our people. People should know that the food they eat and the water they drink will not make them sick..."

"Today we add the cornerstone to this solid foundation [of new laws] with the Food Quality Protection Act. I like to think of it as the 'peace of mind' act, because it'll give parents the peace of mind that comes from knowing that the fruits, the vegetables, the grains that they put down in front of their children are safe. It's long overdue. The old safeguards that protected our food from pesticides were written with the best of intentions, but they weren't up to the job. And as you can see from the vast array of support here across every sector of American life, nobody liked them very much and no one thought that they really worked as they were supposed to. Bad pesticides stayed on the market too long, good alternatives were kept out." (Posted in full at <http://www.ecologic-ipm.com/pandv.html>)

B. Major Provisions of the FQPA

The FQPA incorporated into federal law the major recommendations of the 1987 and 1993 NAS/NRC reports. A new and consistent standard – “reasonable certainty of no harm” – was put in place to govern the review, establishment, and adjustment of all pesticide tolerances. The EPA was directed to place greater weight on the risks faced by pregnant women, infants, and children. New provisions were added to FIFRA to transform the statute’s risk-benefit decision rule to a purely health-based standard for the purpose of tolerance setting. Effective on the date of passage, all new petitions for pesticide tolerances were to be reviewed and approved in accord with the new “reasonable certainty of no harm” standard.

The EPA was also directed to review the 9,721 tolerances on the books to assure they were in compliance with the FQPA’s new safety standard. The agency was responsible for reviewing the riskiest one-third of pesticide tolerances within three years of passage (i.e., by summer 1999). Two-

thirds of existing tolerances were to be reviewed and brought into compliance with the new statute six years after passage (summer 2002). Within 10 years, all tolerances were to be reviewed and adjusted as needed, or by August 2006.

There were four major changes made by the FQPA in how the EPA evaluates pesticide dietary risks and makes tolerance decisions:



- Assure that pesticide tolerances are safe for at-risk populations, particularly infants, children, and the elderly, based on a “reasonable certainty of no harm” standard (i.e., a health-based standard, not cost-benefit-balancing);
- Aggregate exposure to a pesticide from all dietary sources, drinking water, residential, and other routes must be taken into account;
- An added 10-fold safety factor shall be used in setting pesticide Reference Doses (RfDs) to account for the unique risks faced by infants and children, unless the Administrator has solid data supporting a determination that existing RfDs were fully health protective, even for infants, and that exposures were fully and accurately characterized; and
- For pesticides that pose threats to humans through a common biological mode of action (like the organophosphate insecticides), aggregate exposures to all such pesticides must be evaluated together in determining whether a given tolerance is safe.

As a result of these two milestone events in the 1990s, significant progress has been made in refining the accuracy of pesticide risk assessments (Consumers Union, 2001). Bigger and better pesticide exposure databases are now available, and government-sponsored research on the

developmental impacts of pesticides has deepened understanding of both the nature of risks stemming from pesticide exposures, and the levels and distribution of those risks across exposure pathways, foods, and types of pesticides.

CONTEMPORARY INDICATORS OF PESTICIDE EXPOSURE

IV

In the early 1990s relatively little was known about the frequency or levels of pesticides in food as actually eaten, a shortcoming highlighted by the NAS/NRC committee in *Pesticides in the Diets of Infants and Children*. Then-existing government data on pesticide residues had been collected as part of tolerance enforcement programs, and represented residues at the farm gate, prior to washing, shipping, storage, marketing, and food preparation. Relatively insensitive analytical methods were employed.

A. The Pesticide Data Program



To improve the accuracy of pesticide dietary risk assessments, Congress funded the U. S. Department of Agriculture's (USDA) "Pesticide Data Program" (PDP). As recommended by the NAS/NRC, this program focuses on the foods consumed most heavily by children;

and food is tested, to the extent possible, "as eaten" (Agricultural Marketing Service, 2002). Banana and orange samples are tested without the peel; processed foods are tested as they come out of a can, jar or freezer bag.

Over the last 10 years the PDP has tested over 150,000 samples of the 20-odd foods consumed most frequently by children. The most commonly eaten foods, such as milk, apples, apple juice, grapes, oranges, bananas, peas, tomatoes, and strawberries, have been in and out of the program two or more times. Less popular foods such as nectarines and spinach have also been included. In general, the more residues found in one round of PDP testing for a given food, the more likely that food will be added again to the program. About one-quarter of the samples in a given year are processed foods and juices.

The PDP database provides a basis for calculations of the level of pesticide risks, and distribution of relative risks across foods and pesticides, and by food-pesticide combinations. Estimates of how the FQPA and other initiatives have impacted pesticide dietary risks can be made utilizing the PDP dataset, coupled with EPA estimates of each pesticide "Reference Dose" (RfD) or "Population Adjusted Dose" (PAD).² All measures of pesticide dietary risk levels combine in some fashion:

- Estimates of how much food, and which foods are eaten in a day;
- How frequently a food is eaten;
- The percentage of the samples of a given food that contain a residue;
- Average residue levels; and
- The pesticide's toxicity, as measured by its dietary RfD or PAD.

While the PDP dataset is extensive, sensitive, and of high quality, it does not test all foods, nor are the analytical methods used able to detect all pesticides. Still, we believe that the PDP dataset encompasses most of the significant sources of dietary exposures to high-risk pesticides in the U.S. diet.

The frequency of infant and childhood exposures to pesticides is poorly understood by the general public, and indeed by most scientists. According to USDA food consumption surveys, the average American consumes about 3.6 servings of fresh and processed fruits and vegetables per day, of which about two are fresh fruits and vegetables. About 70 percent of the samples of fresh fruits and vegetables consumed in America contain one or more pesticide residues (Agricultural Market Service, 2002; Baker et al., 2002b).

About 75 million Americans are under age 20. Assuming the average young individual in America eats two servings of fresh fruits and vegetables daily, he or she consumes pesticides this way about 105 million times each day. Given that this estimate captures just a portion of fresh foods and ignores exposures via processed foods and juices, the actual number of exposures through fruits and vegetables is probably at least 200 million daily.

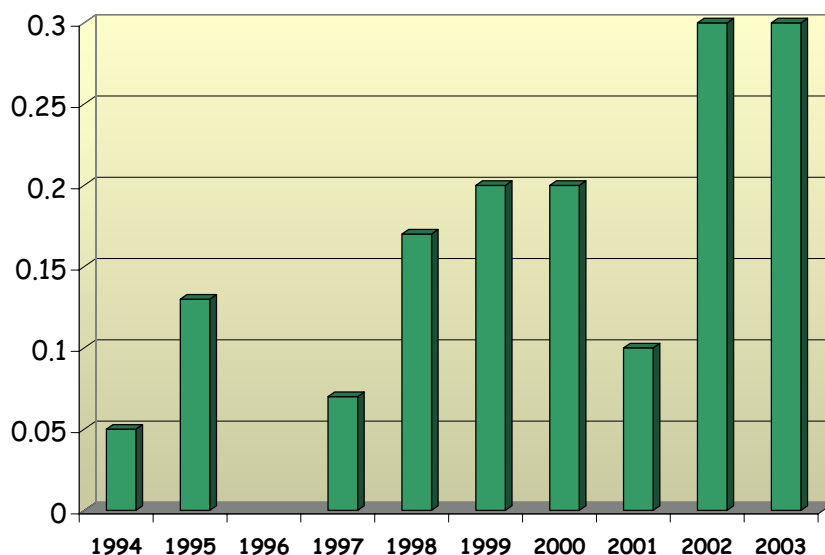
² EPA typically calculates a pesticide active ingredient's "Reference Dose" by dividing a "No Observable Adverse Effect Level" from an animal study by a safety factor of 100. A "Population Adjusted Dose" is the RfD divided by any applicable, additional FQPA safety factor.

In addition to exposures in food, drinking water also contributes significantly to daily pesticide ingestion for millions of Americans. In recent years the PDP has also tested drinking water as it comes out of the tap; the results that follow are from the program year 2003 report (see Appendix M in the PDP report). About 54 percent of drinking water samples tested positive for one or more pesticides and pesticide metabolites. Individuals under age 20 in the U.S. therefore consume about 250 million servings of water daily that contain one or more pesticide or pesticide metabolites (average 6.1 servings of water per capita). Nearly 70 million servings of drinking water consumed daily by young people contain four or more pesticides and/or metabolites.

Figure 1. Percent of PDP samples found to have residues exceeding the established EPA tolerances, 1994 - 2003

Accordingly, the average young American is exposed to more than five servings of food and water daily that contain pesticide residues at or above PDP detection levels. Fortunately, in most cases the levels found are very low and pose modest if any risks to healthy young people.

However, some residues fall in the range where the weight of the evidence points to potential biological impacts, particularly when exposures occur at vulnerable periods of development, or during an illness. A small but growing percentage of residues are found at levels higher than allowed by published tolerances. In the last 10 years the frequency of over-tolerance residues in food has increased 5-fold, from about 0.05 percent to 0.25 percent, as shown in Figure 1. While a seemingly low percentage, one-quarter of 1 percent of 200 million exposure episodes each day would result in about 500,000 over-tolerance exposures. There is no doubt also a significant number of exposure episodes involving drinking water in which residues exceed applicable "Maximum Concentration Limits," or other safety benchmarks. Regulators, the pesticide industry, the food industry, and parents should be concerned about these million or so pesticide exposures every day at levels above what the EPA regards as safe.



While we lack the knowledge needed to accurately calculate the health outcomes triggered by over-tolerance and all other pesticide exposures, we can say with confidence that reducing their prevalence will lessen the frequency and severity of childhood developmental abnormalities, lower the incidence of a cluster of reproductive problems, and will enhance lifelong well-being for thousands of people.

B. OP Metabolites

Since passage of the FQPA in 1996, the EPA has focused on reducing exposures to the organophosphate (OP) class of insecticides. The Centers for Disease Control, and National Institutes

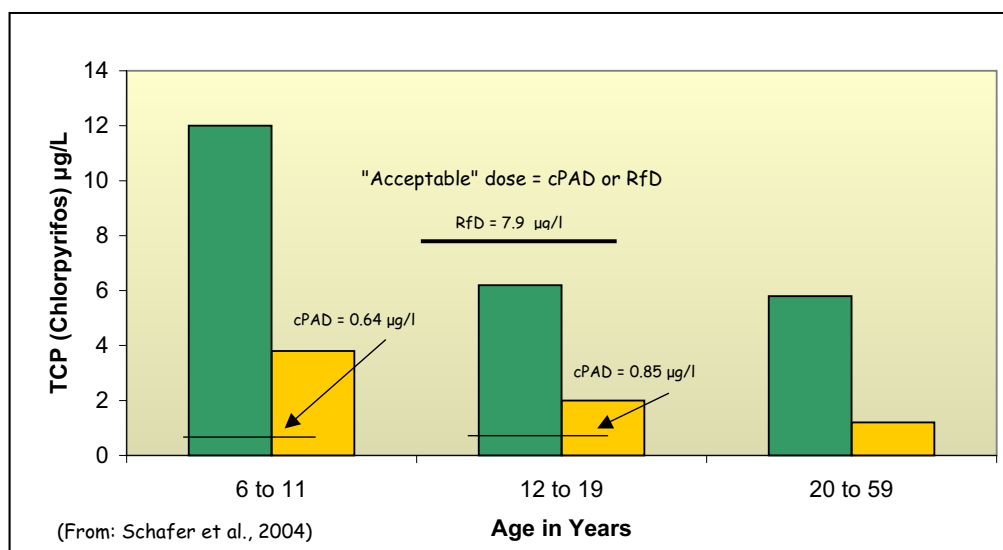
of Health have periodically monitored levels of OP metabolites in urine and blood across the population. In CDC and private surveys of OP metabolites in urine and blood, 90 percent or more of children test positive for usually several of these insecticide metabolites (Adgate et al., 2001b; Centers for Disease Control and Prevention, 2001). As we point out later, drawing on these data, there have been only modest reductions in OP metabolites in the urine across our population, despite 10 years of focus on reducing OP exposures and risk.

A report entitled "*Chemical Trespass*" was issued in May 2004 by the Pesticide Action Network (Schafer et al., 2006). It contained detailed analysis of 2001-2002 NHANES OP urinary metabolite data, and used published methods to estimate exposure levels to parent compounds from creatinine-

Figure 2. Chlorpyrifos exposure above "acceptable" levels in many children (2001 - 2002 NHANES data)

corrected urinary metabolite levels. They focused on chlorpyrifos and its metabolite: 3,4,6-Trichloro-2-pyridinol, or TCP, and found that chlorpyrifos exposures for children ages 6-11 and 12-19 exceeded the EPA's chronic Population

Adjusted Dose (cPAD) by surprisingly wide margins. Geometric mean TCP levels were 3 to 4.6 times higher than the EPA-estimated "safe" dose, as shown in Figure 2. The more heavily-exposed children received daily doses surpassing 10 times the "safe" level.



PRIVATE SECTOR INITIATIVES TO REDUCE CHILDREN'S PESTICIDE RISKS



In recent years there have been encouraging growth in the scope and effectiveness of private sector and farmer-driven initiatives designed to reduce children's pesticide risks. These include:

- Significant progress in the discovery and registration of reduced-risk, biologically-based pesticides;
- Coordinated efforts to develop and implement biointensive Integrated Pest Management systems;
- Marketplace efforts to reward progress toward reduced-risk pest management systems through ecolabels and price premiums; and
- Strong growth in the production, processing, and marketing of organic food.

A. Public Policy Efforts to Promote IPM

Public policy reforms, initiatives, and investments have played a role in encouraging constructive change in each of these areas. The EPA adopted a reduced-risk pesticide registration program in the mid-1990s that cut about two years, on average, off the time from receipt of a registration application to the granting of registrations. In recent years, a majority of the new active ingredients approved by the EPA are reduced-risk and/or biopesticides.³ For example, in FY 2004, 26 new active ingredients were approved: five conventional pesticides, and 21 reduced-risk chemicals, including 14 biopesticides. The EPA has also supported IPM innovation through its "Pesticide Environmental Stewardship Program."

The U.S. Department of Agriculture has funded over the last several years three competitive grant programs designed to support private sector development and adoption of biointensive IPM systems – CAR ("Crops at Risk"), RAMP ("Risk Avoidance and Management Program"), and PMAP ("Pest Management Alternatives Program"). While



well-designed and highly competitive, the programs have been funded at very low levels, allowing only a handful of projects to move forward each year.

There are at least 50 important crops grown in the U.S., each in at least five major production regions facing unique pest management challenges. All 250 crop-region combinations face important weed, insect and disease management challenges in progressing along the IPM continuum, yet the USDA is able to invest, through its IPM-competitive grant programs, in only less than a dozen crops and regions in most years, with most projects focusing on one of the three major classes of pests.

Adoption of organic farming systems and the certification of organic foods have been advanced by the USDA's implementation of the Organic Food Production Act, passed as part of the 1991 farm bill. The "National Rule" governing organic production and certification was finalized by USDA in 2001, and has put in place clearer rules governing the necessary steps to prevent conventional pesticides moving into organic production fields. It has improved and broadened compliance and enforcement efforts.

Private foundations have played a key and catalytic role in supporting new partnerships focused on adoption of biointensive IPM. The Pew, C.S. Mott, W. Alton Jones, and Joyce Foundations have, in particular, invested heavily in IPM innovation for more than a decade as a way to reduce environmental damage and public health risks stemming from high-risk pesticide use. The emergence of agricultural biotechnology as a high-visibility issue, however, led most of these foundations to redirect investments in IPM to work on the impacts of biotechnology.

Several food companies have encouraged IPM innovation and rewarded it in the marketplace. The Wegman's chain of supermarkets developed the first credible IPM food product-labeling program in New York State, in cooperation with the Cornell Statewide IPM program. The Raley's supermarket chain on the West Coast, and H.E. Butt supermarkets in the

³ "Biopesticides" include naturally occurring substances that control pests (biochemical pesticides), microorganisms that control pests (microbial pesticides), and pesticidal substances produced by plants containing added genetic material. Biochemicals work through a non-toxic mode of action and include microbial pesticides, pheromones, and a host of plant regulators. Most "biochemical" pesticides also qualify for expedited review under the EPA's "reduced risk" policy.



Southwest, both adopted pesticide residue testing programs in the early 1990s. Other chains have followed.

The Gerber Products Company has invested steadily since the 1980s in IPM systems and quality control procedures designed to assure no detectable pesticide residues in finished product. Stemilt Growers in the Pacific Northwest is a major grower of tree fruit crops. In 1989 it started to develop the first program in the U.S. designed to encourage grower adoption of IPM, coupled with use of lower-risk pesticides, through what is still called the “Responsible Choice” program. The company remains a leader in supporting development and adoption of IPM. It has a growing presence in the organic market, and has achieved positive results in the marketing of high-quality, value-added fruits to food-safety sensitive markets in the Pacific Rim.

The Wisconsin potato industry initiated one of the more ambitious, broadly supported biointensive IPM programs in 1995 involving the World Wildlife Fund, the state’s potato grower association, and the University of Wisconsin. The WWF-WPVG-UW collaboration is still going strong after a decade and has led to the creation of an ecolabel certification program, called “Protected Harvest.” Protected Harvest has received the highest rating possible by the Consumers Union’s ecolabel program.

It is difficult to rigorously quantify the relative contributions of these various private sector initiatives in reducing children’s dietary pesticide

risks, just as it is challenging to document fully the impacts of the FQPA on risk levels and the distribution of risks across foods. Fortunately, the residue data generated by the USDA’s “Pesticide Data Program” provides a foundation for tracking changes in dietary risks over time.

B. New Chemistry

Registration of reduced-risk and biochemical pesticides has helped reduce pesticide dietary risks over the last 15 years. Passage of the FQPA has accelerated somewhat the shift away from a few

high-risk organophosphate (OP) insecticides, especially methyl parathion and chlorpyrifos, and to a combination of reduced-risk chemistries and biointensive IPM.

Important reduced-risk insecticides include the following classes and active ingredients:

- Nicotinyl insecticides including imidacloprid (Admire), acetamiprid (Assail), and thiamethoxam (Actara);
- Insect growth regulators including tebufenozide (Confirm), methoxyfenozide (Intrepid), buprofenzin (Knack), and pyriproxyfen (Courier);
- The actinomycete-based biopesticide spinosad (SpinTor, Conserve, Tracer for conventional farmers; Entrust for organic producers);
- Spiromesifen (Oberon);
- Pymetrozine (FulFill);
- About 10 pheromone confusion products used in mating-disruption systems;
- About six microbial biopesticides containing various *Bacillus thuringiensis* toxins; and
- Indoxycarb (Avaunt).

Of the 27 insecticides noted above, all but spinosad and imidacloprid rarely appear as residues in food. Each acre of crops treated with these products lessens the likelihood that an OP or carbamate will be used and remain on harvested foodstuffs.

C. Shift to Biointensive Pest Management

Integrated Pest Management systems range from relatively simple to highly complex. In a given region and on farms producing a given crop, it is useful to think of and measure IPM adoption along a continuum: from “no” or “low-level” IPM, to “moderate” or “medium” levels of adoption, to “high” or biointensive IPM. As growers progress along the IPM continuum, the sophistication and effectiveness of the preventive practices within their IPM systems tends to increase, and their reliance on pesticides, especially highly disruptive products, tends to decrease.

The measurement of IPM is challenging because across crops and regions, the nature and number of IPM practices needed in a given year are driven by levels of pest pressure, the availability and performance of resistant plant varieties, the cost and efficacy of registered pesticides, and the cost and efficacy of cultural, mechanical and biocontrol options. Farmer and pest manager experience and skill in managing pests also has a major impact on IPM system design, costs, and efficacy.

Biointensive IPM systems encompass sufficient preventive practices to shift a major share of the pest control burden away from chemicals. Even in organic production systems, some use of organically acceptable pesticides is often required to sustain adequate control and avoid major economic losses in high-value fruit and vegetable crops.

Systems to measure the degree of adoption of IPM have been developed to:

- Track the progress of growers along the IPM continuum and identify technical hurdles;
- Assess relative dependence on plant resistance (genetics) and cultural, mechanical, biological, and chemical pest management interventions;
- Identify linkages between IPM adoption and pesticide use and impacts;
- Analyze the impacts of specific new technologies or policy innovations; and
- Develop and utilize IPM standards as part of ecolabel programs.

Measurement of IPM is facilitated by information on pest complexes and levels of pest pressure, and in particular, by factors triggering changes in pest pressure. A few crop-specific projects have

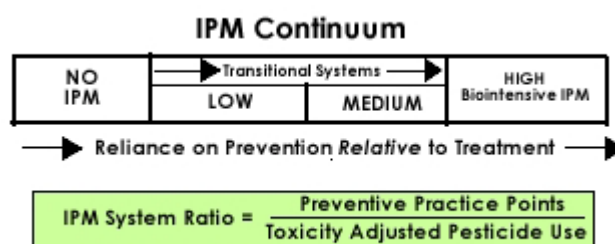
measured levels of IPM adoption and linkages to pesticide use and found highly significant differences between the toxicity of pesticides applied at the “low” end of the IPM continuum, compared to the biointensive end (for example, see the technical reports of the WWF-WPVGA-UW potato IPM collaboration at <http://ipcm.wisc.edu/bioipm/>).

As part of the National IPM Initiative started in 1994, the USDA identified the importance of developing a credible, data-driven IPM measurement system (Benbrook et al., 1996; Benbrook 2000; Benbrook 2005). Progress toward an IPM measurement system has been slow, however, and no national assessment has been undertaken. The USDA has not made the investments needed in measurement methodology and data that will be required in order to comprehensively estimate the percentage of acreage farmed at various points along the IPM continuum.

Based on IPM project status reports, we estimate that 10 percent to 25 percent of the acreage producing high-value fruit and vegetable crops is farmed in or near the biointensive zone along the IPM continuum. About the same share of acreage is still managed with chemical-intensive systems at the “low” end of the IPM continuum, and the balance of acreage lies between these two extremes.

Clearly, IPM has made important contributions to reducing reliance on high-risk pesticides, but progress along the IPM continuum requires much effort and occurs slowly. Sustaining progress requires ongoing investment and system innovation, especially when new pests become established or resistance undermines a once-effective and safe pesticide.

Figure 3. The IPM Continuum



Public and private investments in IPM are clearly falling far short of need and are probably falling overall. The infrastructure required to profitably practice IPM in the field is at best holding its own. Despite years of effort by the last three

Administrations to increase federal IPM funding, Congress has refused to provide more than token increases. For these reasons there is little basis to expect major additional reductions in pesticide dietary risks from IPM innovation on conventional farms and ranches, at least not without some additional pressure or inducements for change (i.e., regulation, new technology, or marketplace incentives).

D. Food Marketplace Incentives and Ecolabels

Marketplace incentives for pesticide risk reduction currently play a modest role in reducing pesticide risks. The major reason is that the acreages enrolled in all ecolabel programs combined likely represent less than 3 percent of U.S. harvested cropland.

“Certified organic” is by far the major ecolabel in terms of acreage enrolled and share of total food sales, accounting for close to 2.5 percent of sales and about 1.5 percent of acreage. Still, food companies large and small are actively pursuing a number of ecolabels and health-claims to win and hold market share. The scope and impact of ecolabel programs, especially “certified organic,” are bound to expand significantly and perhaps exponentially.

There are two wild cards that will determine how fast organic production and other ecolabels expand their reach into the American food industry -- public’s perceptions of the role diet can play in health promotion, and second, the public’s awareness of the impacts of agricultural chemical and animal drug use on diet-related diseases and health problems. Rates of growth in sales of organic food will increase if consumers become convinced that how conventional food is grown adversely impacts the quality and safety of food.

Current food ecolabel programs make two sorts of claims regarding pesticide use and risks. One set is based on food safety outcomes. The second set of claims refers to how a crop is produced. Food ecolabels fall into one or more of three categories:

- “Pesticide free” or “No Detectable Residues” in food (NDR);

- Food grown using IPM systems and/or environmentally friendly pesticides and management systems; and
- Certified organic.

Empirical data on the impact of these three types of programs on pesticide residue levels and frequency can be obtained from the USDA’s “Pesticide Data Program.” The information recorded on each sample of food tested by the PDP is supposed to include any market claim associated with a given food item, such as “organic,” “IPM-grown,” “No Detectable Residues” or “pesticide free.” In the first years of the PDP, market claim data was not consistently recorded or reported, whereas in recent years, this information is provided for most samples. As a result, PDP outcomes make it possible to compare the frequency and levels of pesticide residues by market claim.



The first and still only peer-reviewed study comparing pesticide residues in organic, IPM-grown and NDR, and conventional foods, was published in *Food Additives and Contaminants* (Baker et al., 2002a). It draws on three datasets: 1994-1999 PDP data; residue testing by the California Department of Food and Agriculture; and Consumers Union testing of four foods. Baker et al. concluded that residues are far more frequent in conventional and IPM/NDR foods than organic samples; multiple residues are more common in conventional and IPM/NDR samples, compared to organic; and, levels found in conventional and IPM/NDR samples were significantly higher than corresponding levels in positive organic samples.

Consistent and statistically significant differences were found in each of the three datasets, lending confidence to the overall results. The pattern of residues in IPM and NDR samples was closer to conventional food than organic food.

Residues in Organic Food

A similar, updated comparison of pesticide residues in conventional, IPM/NDR, and organic foods, was carried out in 2004 by The Organic Center (TOC) in its first “State of Science Review” (Benbrook, 2004). The Center’s analysis covered PDP results through 2002. One or more residues were found in 69 percent of conventional fresh fruit and vegetable samples, 46 percent of IPM/NDR-grown foods, and 18 percent of organic samples.

The Center is updating and will reissue its SSR on pesticide residues (Benbrook, 2006). The new report contains two more years of PDP data and expanded discussion of pesticides used on organic farms. From 1993-2004, 66 percent of the conventional samples tested by the PDP had one or more residues and 17 percent of the organic samples contained residues. Pesticides were present on 45 percent of the IPM/NDR samples, indicating that the IPM/NDR pattern of pesticide use is closer to the conventional system than the organic.

Similar results were obtained from testing done just in 2004. Seventy-eight percent of the conventional samples had residues, while 16 percent of the organic samples also tested positive.

As the data cited above shows, organic food is not free of pesticide residues, despite rules prohibiting applying most synthetic chemicals to organic crops. About 15 percent to 20 percent of organic fruits and vegetables tested by the PDP in recent years are found to contain residues of prohibited synthetic pesticides, a percentage that has declined in recent years.

Why do organic samples sometimes contain residues of synthetic pesticides?

Pesticides are often present and mobile across agricultural landscapes. Positive organic samples typically contain low levels of pesticides used on nearby conventional fields that have been carried over by wind drift.



Pesticides are also carried in dust blowing from one field to another, and sometimes move in fog.

Another cause of cross-contamination is the use of tainted irrigation water. When irrigation water contaminated with low levels of pesticides is applied on an organic field, organic crops are sometimes affected.

Some insecticides that were applied 20 or more years ago on conventional farms can still be found in the soil, even after conversion to organic management. Residues of persistent organochlorine insecticides like DDT, dieldrin, and chlordane are among the most common residues found in certain root crops and in most animal products.

Lastly, post-harvest contamination sometimes occurs in storage facilities when, for example, a box of insecticide-treated conventional apples is placed too close to a box of organic apples on a truck or in the store (Baker et al., 2002). The very small share of organic samples that are found to contain a residue at a level comparable to conventional food likely reflects inadvertent mixing of produce, laboratory error, mislabeling, or fraud.



Pesticide Use on Organic Farms

Certified organic food is grown in compliance with a comprehensive set of standards that includes prohibition against the use of most synthetic pesticides. Organic farmers may and often do apply sulfur, oils, copper fungicides, pyrethrins, *Bacillus thuringiensis* (Bt), soaps, certain microbial pesticides, spinosad, and pheromones, to manage pests.

By volume, the major pesticides used in organic and conventional agriculture are sulfur, horticultural/petroleum distillates, and oils. Sulfur is the most common pesticide residue present on conventional and organic produce, but it is never tested for because it is exempt from the requirement for a tolerance and poses essentially no risk through the diet. Copper-based fungicides are also important for conventional and organic fresh fruit and vegetable growers. Copper residues are not measured because copper is an essential nutrient and regarded by the EPA as harmless at the levels ingested as food residues.

These natural pesticides are used in similar ways for comparable reasons on organic and conventional produce farms. Only one pesticide commonly used on organic fruit and vegetable farms poses significant potential risks: pyrethrum, a botanical insecticide. Though highly toxic, pyrethrum pesticides degrade rapidly (within hours) after spraying, and rarely leave behind detectable residues. Also, they are applied at very low rates per acre, about one-fiftieth to one-one-hundredth the rate of OP insecticides.

A survey of organic farmers carried out by the Organic Farming Research Foundation found that only 9 percent of 1,045 organic farmers applied botanicals "regularly" (mostly pyrethrum and neem), and that 52 percent never use them, 21 percent use them rarely, and 18 percent "on occasion" (Walz 1999).

Government pesticide residue monitoring programs do not test for most natural and biochemical pesticides approved for use by organic farmers, because the EPA has exempted these products from the requirement for a tolerance, and because there is no basis for food safety concerns, given how these natural products are used on organic farms and their typically short environmental half-lives.

NDR-Based Ecolabels

Some ecolabels are based on claims of “No Detectable Residues,” and are often called “NDR” or “pesticide free” programs. The best-known NDR program is run by Scientific Certification Systems (SCS), an Oakland, California-based company. During the 1994-2002 period covered in the Organic Center analysis of PDP residues in food, the SCS “NutriClean” program used an NDR standard of 0.05 ppm for a given residue in a given food.

The “pesticide free” claims associated with NDR programs are vulnerable to legal challenge since such claims are misleading. This is because “pesticide free” actually means “free of pesticides above a given level (i.e., 0.05 ppm) at the time food is purchased in a store.” Residues are often considerably higher than 0.05 ppm when the food is harvested. Residue data on NDR and conventional produce suggests that pests in fields meeting an NDR standard are often managed in much the same way as pests in nearby conventional fields growing the same crop.

The 0.05 ppm level that corresponds to “No Detectable Residues” actually masks some pesticide residues of toxicological concern. Azinphos-methyl residues in apples are among the major contributors to contemporary organophosphate dietary risk, yet the mean residue level found in PDP testing ranges annually between 0.03 ppm and 0.06 ppm. Methamidophos in tomatoes is another risk driver, with mean residues typically in the same range.

For the approximately two dozen pesticides with acute or chronic Reference Doses at or below 0.0001 mg/kg per day, tolerance levels must be set at 0.01 ppm or lower to meet the FQPA’s new safety standard. EPA actions on high-risk OPs under the FQPA have, in general, adhered to this rule of thumb; in the case of chlorpyrifos residues in grapes

and apples, the EPA lowered the existing tolerances 100-fold and 150-fold to 0.01 ppm for these crops.

NDR-based programs must confront another problem arising from the uses and residue profiles of recently registered biopesticide alternatives. Spinosad, kaolin clay, and harpin proteins are examples of reduced-risk biopesticides with attractive environmental and toxicity profiles. The first two of these biopesticides are approved for organic production, yet some fruit and vegetable uses will result in residues above 0.05 ppm.

Eco-friendly Farming System Claims

Some ecolabels are based on claims regarding the use of eco-friendly production systems and pesticides, sometimes coupled with assurances that certain high-risk pesticides are not used. The goals addressed in some ecolabel programs are expansive, even comprehensive, and may include:

- Pesticide use and risks;
- Erosion control and sedimentation;
- Manure management and livestock husbandry;
- Water quality, and water use and conservation;
- Riparian area management;
- Preservation of wildlife habitat; and
- Worker safety and worker quality of life issues.

The Food Alliance is the best-known example of a comprehensive program. Other programs are more focused and narrow in terms of the crops and regions covered and the types of environmental issues addressed. The Pacific Northwest’s “Salmon Safe” program is an example of a narrowly focused program that strives to achieve a single, well-defined outcome of broad interest to people in the region. An excellent overview of existing ecolabel programs can be found on the Consumers Union ecolabel website, www.eco-labels.org.

Ecolabel programs based on production system claims typically focus on adoption of prevention-based, biointensive IPM. Programs strive to identify core biointensive IPM practices. Certification standards are linked to the adoption of some portion of identified, proven bio-IPM practices.



The requirement for adoption of biointensive IPM practices can serve an educational function and allows farmers to project what program enrollment will entail and cost, and whether alternative systems and technology will work acceptably within their farming system. In practice, biointensive IPM systems are extraordinarily complex and dynamic, and are difficult to capture in a “check list” of practices. Differences from one season to the next, or one production region to another, can dramatically alter pest pressure and the efficacy of various pest management practices. Some ecolabel programs penalize farmers for not adopting practices that they do not need in a given year, because of a lack of pest pressure.

“Do Not Use” Lists

Some ecolabel programs incorporate a “Do Not Use” (DNU) list, as well as a “Use with Restrictions” list (i.e., restrictions in addition to those on pesticide labels). The WWF-WPVGA-UW potato IPM project initially identified a dozen “Do Not Use” pesticides in 1996, as well as another half-dozen that could be used only “with restrictions.”

Ecolabel programs that adopt risk-averse, conservative criteria for placement of pesticides on a DNU list can dramatically reduce risks. Any program in the late 1990s, for example, that placed fruit and vegetable crop uses of methyl parathion and chlorpyrifos onto their DNU list could have locked in substantial risk reduction in advance of EPA actions in 1999 and 2000.

The DNU lists incorporated in most ecolabel programs to date, however, include mostly high-risk pesticides that are obsolete and rarely used. The Gerber Products DNU list is a notable exception, as is the list adhered to by the WWF-WPVGA-UW collaboration.

“Use with Restrictions” lists typically set out a specific set of circumstances in which a moderate to high-risk pesticide may be used. The two principal criteria leading to placement on the WWF-WPVGA-UW collaboration’s “Use with Restrictions” list are:

- Dealing with a “pest management emergency”; or
- The need to incorporate a pesticide within a rotation of active ingredients as called for in a university-recommended resistance management plan.

Incorporation of a “Use with Restrictions” list in a set of ecolabel program standards can complicate annual administration of ecolabel programs, but can also markedly enhance the willingness of farmers to join programs.

E. Essential Ingredients to Reduce Risks Through Ecolabels

While ecolabel programs currently have a modest impact on pesticide risk reduction measured at the level of the food industry, their importance and impact could grow appreciably. Accordingly, it is important to sharpen focus on the claims made by ecolabel programs, and link claims to changes in farm management practices required of program participants.

The Consumers Union administers the most comprehensive ecolabel evaluation program in the country (<http://www.eco-labels.org/home.cfm>).



CU applies five criteria in rating the meaningfulness of ecolabels:

- Is the label verified?
- Is the meaning of the label consistent?
- Are the label standards publicly available?
- Is information about the organization publicly available? and
- Is the organization free from conflict of interest?

Building on the criteria set forth by CU and the experience and accomplishments of existing ecolabel programs, there appear to be six essential ingredients for a pesticide-related ecolabel program to deliver meaningful pesticide risk reduction.

1. There must be scientific basis and data-driven process to identify the pesticide risks that the program is striving to reduce, and hence the pesticides that may and may not be used.
2. Risks targeted for reduction must be quantifiable at the field or farm level in some sort of baseline from which reductions in risk can be calculated.
3. Credible risk indicators must be established that can serve as a proxy for the real-world risks that an ecolabel program is striving to reduce (e.g., impacts on salmon or birds, farm worker poisonings, dietary risks, or a combination of multiple risks).

4. Standards must set forth acceptable and unacceptable levels of risk stemming from pesticide applications on a given field. The standards can be based on direct measures of risk – poisoning episodes, residues in food, bird kills – or on indicators of risk, such as aggregate pesticide toxicity units per acre.

5. Compliance with standards must be independently verified by a third party that is granted access to information needed to assess field-level performance relative to stated standards and requirements.

6. All aspects of the program must be transparent and accessible to growers, consumer and environmental organizations, interested members of the public, the farm community, and regulators.



There has been progress in reducing pesticide dietary risks since the passage of the FQPA. Private sector initiatives have played a major role in facilitating this progress, although it is almost certain that the regulatory pressures imposed by the FQPA accelerated adoption of

both reduced-risk and biopesticide alternatives, and biointensive IPM and organic management systems.

The pesticide industry deserves credit for the investments it made and foresight it displayed by making the effort in the 1980s required to discover, register, and bring to market in the 1990s over two-dozen effective, reduced-risk and biochemical insecticides. These new products have allowed U.S. fruit and vegetable farmers to lessen reliance on high-risk OP and carbamate insecticides. They have provided farmers essential tools to deal with resistant pest populations and lower farm worker risks, and they have provided alternatives when regulation has driven older, but still effective pesticides off the market. While many growers have shifted to these newer, reduced risk alternatives, and many others have not and continue to use the cheapest pesticide available for a given job.

Government and private efforts to expand adoption of IPM have had modest impact on pesticide dietary risks in the last decade because projects have focused on very few crop-region-

pest combinations, and the acreages impacted by project results remain limited. IPM programs and infrastructure are grossly under-funded and must struggle just to keep up with emerging challenges.

Only a small percentage of growers have adopted prevention-based biointensive IPM systems. The dominant focus of most IPM research remains sustaining the efficacy and affordability of chemical-based systems. IPM remains a necessity for successful pest management, but has not proven to be a major force for change in terms of reducing pesticide dietary risks. The impact of IPM innovation has surely been dwarfed by the impact of new synthetic chemistry and biopesticide technology.

The impact of ecolabel programs on pesticide dietary risks is also modest relative to the whole food system, largely because less than 3 percent of harvested acreage is enrolled in such programs, with certified organic cropland accounting for over half this total. On the other hand, cropland transitioned to certified organic production essentially eliminates pesticide dietary risks on each acre enrolled. It offers the strongest guarantee that pesticide risks will be decisively reduced.

The Role of Economics

Economics has played, and will continue to play, a major role in shaping the impact of private sector initiatives to reduce pesticide dietary exposures.

For most fruit and vegetable crops, growers could have adopted low-risk pesticide alternatives in the mid-1990s, but many did not do so because the cost of older, higher-risk pesticides was usually less than



half of the cost of systems based on safer, newer alternatives. Only a small percentage of growers were willing to adopt safer technology when first available, despite the increase in costs and reduction in per-acre profits.

The combined effects of pest resistance to pesticides and regulation have been important in many areas in driving major changes in pest management systems, and have forced growers to move along the IPM continuum toward more prevention-based systems.

Recent consumer surveys show clearly that a lack of supply and high price premiums are holding back growth in the sales of organic food. If economies of scale common in the conventional food processing, distribution, and marketing systems become accessible to organic farmers and food companies, price premiums will narrow appreciably

and demand will grow. Whether and how supply will grow in step with demand remains to be seen, given the three-year transition period required to convert conventional cropland to certified organic production.

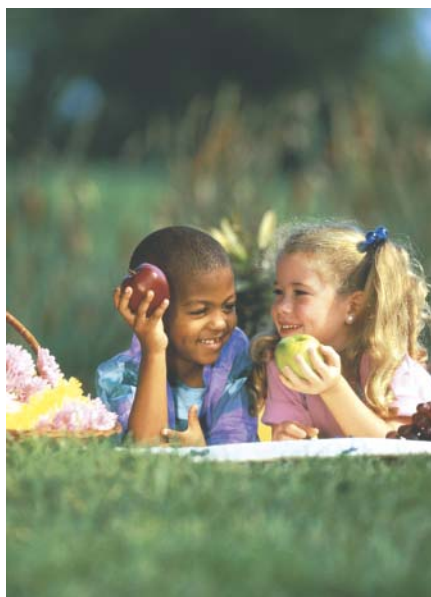
Deeper consumer awareness of the impacts of food production systems and diet on health could trigger strong growth in organic demand and production. If faster growth is concentrated in high-value fruits and vegetables that are important in children's diets, organic production could lead to significant reductions in pesticide dietary exposure and risks. Most of the fresh produce and milk served to children could be produced organically within one to two decades, if a concerted effort was made to accomplish this goal. There is no other conceivable scenario in which pesticide dietary risks facing infants and children could be largely eliminated in the same time frame.

IMPACTS OF THE FQPA ON DIETARY EXPOSURES AND RISK

VI

The EPA faced a daunting task in implementing the FQPA. A number of science policies had to be developed to translate the law's new provisions into risk assessment procedures and decision-making rules. Much new data had to be compiled and integrated in ways to support aggregate and cumulative risk assessments.

There were 9,721 pesticide tolerances in place when the FQPA passed, and 1,780 involved economically important food uses (based on applications to 1 percent or more of national crop acreage). Of these, 381 were covered by pesticide residue data collected by USDA's PDP. According to dietary risk analyses carried out by Consumers Union, 125 of these 381 pesticide-food combinations accounted for 99 percent of dietary risk based on PDP residues, and of these, 63 were organophosphate (OP) insecticides. This is why the EPA has focused so much attention on the OPs in the FQPA implementation process.



The EPA regulates dietary risks under the FQPA at the 99.9th percentile level of exposure, based on a probabilistic distribution of dietary exposures. Monte Carlo simulation methods are used to generate hundreds of thousands to millions of "eating day episodes" for a person of known weight. A simulated estimate of pesticide exposure per kilogram of bodyweight is made based on the actual foods reported as eaten by the individual in the USDA's food consumption survey. Each food is also linked to a distinct record in the PDP residue data file for the same food. The computer randomly selects a residue value, such that the most common levels are chosen more frequently, and higher residue levels are picked only as frequently as they appear in PDP sampling.

A person's daily exposure to a given pesticide is estimated by summing exposures across all foods. The results are expressed in milligrams of

pesticide ingested per kilogram of bodyweight and are arrayed from the highest exposure to the lowest.

Under FQPA science policies, all tolerances covering food uses of a pesticide are regarded as acceptable if the child at the 99.9th percentile level of the exposure distribution curve ingests less of the pesticide than "allowed." The amount of OP exposure allowed by the FQPA's "reasonable certainty of no harm" standard is based on the pesticide's acute Population Adjusted Dose (aPAD). Risk reduction measures are typically invoked in cases in which the EPA judges that exposures at the 99.9th level exceed the applicable aPAD.

Typically, the age group that is exposed to the greatest amount of pesticides per kilogram of body weight is 1- to 2-year-old children, or children through age 13. This is why the EPA has focused so heavily on children's exposures and risks throughout the FQPA implementation process, and why the impacts of the FQPA should be judged relative to changes in risks to children.

A. Impacts of the FQPA's 10-X Provision

The FQPA requires the EPA to impose an added 10-fold safety factor when setting acceptable levels of exposure to pesticides and when establishing tolerances. In practice, the EPA does this by dividing existing acute and chronic Reference Doses by the applicable FQPA safety factor, reducing allowable aggregate exposures up to 10-fold. The resulting estimates of acceptable daily exposure are called acute and chronic "Population Adjusted Doses" (aPADs, cPADs, respectively), and are reported in milligrams of pesticide per kilogram of bodyweight.

An FQPA safety factor less than 10-fold can be adopted if the Administrator has solid data supporting three judgments:

- A pesticide is no more toxic to young animals than adults;
- A pesticide's Reference Dose is fully protective of infants and children; and
- The agency has ample data to accurately estimate exposures and risks from all pathways.

In many cases the EPA lowered the FQPA safety factor to 3 or zero. Safety factors other than zero, 3, and 10 were periodically considered, but never applied. The EPA pledged to base its 10-X decisions on the "weight of the evidence."

Consumers Union (CU) released a report in 2001 analyzing the impacts of the FQPA five years after its passage (Consumers Union 2001). It assessed the EPA's 10-X decisions on OP insecticides, the agency's major focus in the first five years of the FQPA implementation process.

Out of 49 OPs subject to FQPA review, five were not registered in the U.S. and were not evaluated. Because of the acute nature of OP cholinesterase inhibition, the EPA chose to establish both acute and chronic PADs. By the end of 2000, acute PADs were established for 38 OPs, and chronic PADs for 44, for a total of 82 10-X decisions on the OPs.

CU reports that the EPA retained a full 10-X added FQPA safety factor in only 13 of the 82 10-X decisions on OPs, or just 16 percent. In another 16 percent of these decisions, the EPA retained a 3-X added FQPA safety factor. Combining cases with a 3-X and 10-X FQPA safety factor, an extra safety factor designed to ensure "reasonable certainty of no harm" to children was retained by the EPA in one-third of its decisions on OP Population Adjusted Doses. In two-thirds of its OP PAD decisions, the agency set the FQPA safety factor at zero. These decisions remain controversial.

The most commonly cited reason for retaining the full 10-X was the absence of an adequately designed developmental neurotoxicity (DNT) study (10 of 13 cases). Evidence of neurotoxicity and/or evidence of heightened sensitivity of offspring or prenatal/developmental toxicity were the next most frequent reasons the EPA cited for retaining an extra safety factor.



B. Methods to Track Changes in Pesticide Dietary Risks

The need to track the impact of the FQPA on children's dietary exposure was recognized in the fall of 1996, as the EPA initiated the implementation process. Consumers Union (CU) was successful in securing foundation funding for a multi-year FQPA evaluation project that ran from 1997 through 2001.

A first key task in evaluating the impact of the FQPA is to draw on the PDP database, coupled with information on pesticide toxicity from the EPA's pesticide registration program, to establish a baseline of pesticide dietary risks in the mid 1990s when the FQPA passed. Then, changes in risk levels from that baseline can be projected, and to the extent possible, linked to private sector initiatives, the impacts of EPA regulatory decisions, or both working in concert.

Consumers Union "Toxicity Index"

The Consumers Union project team developed a methodology to track changes in pesticide dietary risks (Consumers Union 2001; Groth et al., 2000). A "toxicity index," or TI score was calculated for specific pesticide-food combinations in a given year, based on the frequency and mean concentrations of

residues found in PDP testing, and the EPA's then-current assessment of pesticide "Reference Doses" (RfDs) and "Population Adjusted Doses" (PADs).

EPA Office of Inspector General Project

Given that the 10 years provided by Congress for full implementation of the FQPA ends in August 2006, the EPA's Office of Inspector General (OIG) initiated in 2004 a multi-phase project assessing the impacts of the FQPA. Two of three scheduled reports have been issued.

The first EPA-OIG evaluation report is entitled "Changes Needed to Improve Public Confidence in EPA's Implementation of the FQPA" (OIG Report No. 2006-P-0003, October 19, 2005), and the second report is called "Opportunities to Improve Data Quality and Children's Health through the FQPA" (OIG Report No. 2006-P-0009, January 10, 2006). The third report is due out in mid-2006 and will assess the impacts of the FQPA on various measures of dietary risks, among other impact indicators.

As part of the analytical work supporting its third report, the OIG asked Benbrook Consulting Services to refine and update the original CU analysis of the impact of the FQPA on dietary risks. In doing so, the CU methodology was modified to produce a "Dietary Risk Index" (DRI), the toxicology database was updated to reflect Reference Doses and PADs current in 2005, and three more years of PDP pesticide residue data were included. The OIG

analysis covers pesticide residue and risk levels from 1994 through 2003. See Appendix A for a more detailed description of the DRI methodology.

C. Trends in Dietary Risks Since 1994

The analysis of the impacts of the FQPA on dietary risks carried out for the EPA Office of Inspector General focused on 16 fresh fruits and vegetables that had been tested four or more years in the PDP. For each food, DRI scores were estimated for each pesticide found in the food, and then aggregated across all pesticides found. The analysis was carried out for three sets of residues: those in domestically grown food, imported foods, and all PDP samples combined.

The most reliable indicator of trends in aggregate DRI scores is the average DRI score per food tested in a given year. This is because of significant variation in the number of the 16 foods tested by PDP in a given year. For example, in 1997 and 1998 only three of the 16 foods were tested, whereas 10 of the 16 were tested in domestic samples in 1994, 2000, 2001, and 2002.

Average domestic DRI scores per food tested fell from 225 in 1994 to 65 in 2003, while the average of DRI scores per food for imports rose from 98 to 244. Trends in domestic and imported average DRI scores are shown in Figure 4. Clearly, these data show a pronounced shift in residues and risk from domestically grown food to imports over the last decade.

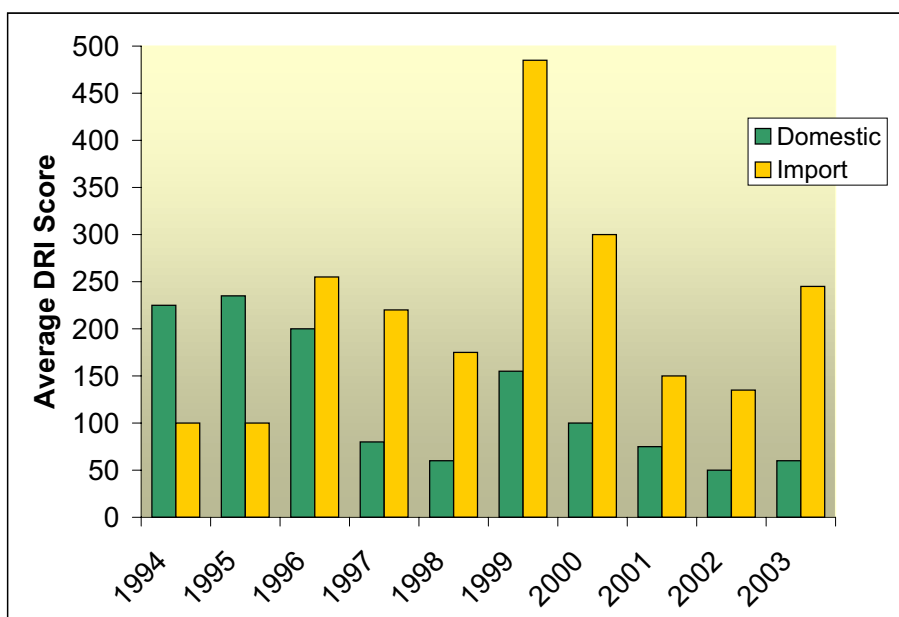


Figure 4. Average DRI Score, Domestic and Imports, 1994-2003

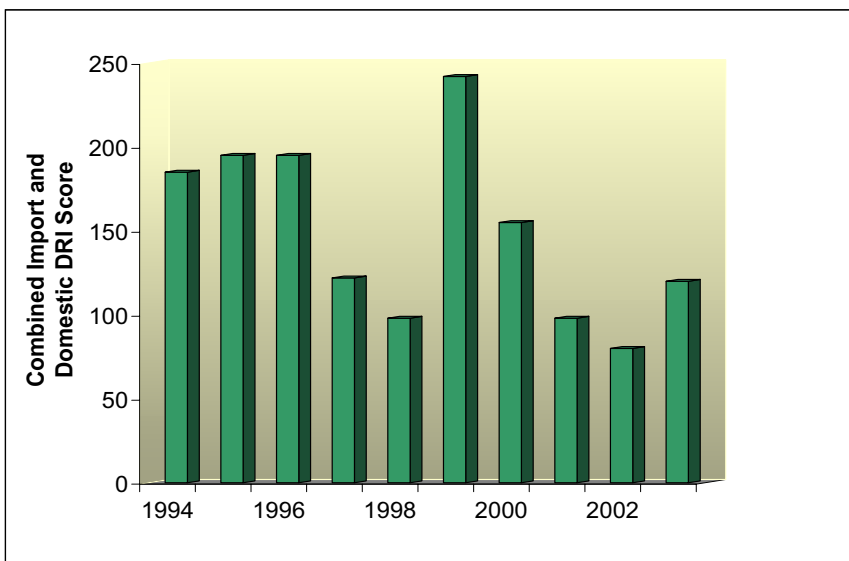


Figure 5.. Combined Import and Domestic DRI Score, 1994-2003

Figure 5 shows the average combined DRI scores per food tested in a given year. Overall combined DRI scores have fallen from 191 to 126, a 34 percent decline. Substantial progress has been made in reducing exposure and risks in some foods. For example, combined apple DRI scores have dropped from around 300 to less than 50, a reduction that was largely brought about by regulatory actions taken to end methyl parathion use on apples and severely restrict chlorpyrifos use.

D. EPA's Cumulative Risk Assessment of the OPs

In response to requests from interested parties, the EPA released detailed results of its June 2002 cumulative risk assessment (CRA) of the OPs. The data allow assessment of the distribution of risks across foods, pesticides, and food-pesticide combinations. Key insights include:

- Eight of 30 OP insecticides accounted for 97 percent of total estimated OP-related risk;
- A single insecticide (dimethoate and its metabolite omethoate) accounted for 47 percent of total risk, largely from residues in just two foods, grapes and apples;
- Grapes, apples and pears accounted for over three-quarters of total risk; and
- Fresh fruits and vegetables accounted for the vast majority of exposure and risk.

The June 2002 OP-CRA confirmed Consumer Union's earlier finding -- a relatively small number of

OP insecticide uses account for the majority of risks faced by infants and children. Grapes, in particular, emerged as a major risk driver.

E. Growing Importance of Imports

In most of the United States, consumers rely on imported fresh fruits and vegetables for three to five months each year. Residue data collected by the USDA's PDP identifies the geographic origin of each sample, making it possible to assess risk levels in, for example, imported grapes, apples, or tomatoes, compared to domestically grown produce.

The EPA's cumulative risk assessment of the OPs identified dimethoate, and its metabolite omethoate, in grapes as by far the major OP risk driver, accounting for 44 percent of total OP risk. When all positive dimethoate grape samples in the PDP database are ranked from highest to lowest, 94 of the top 100 residue values were found in imported grapes. Likewise, 2002 PDP testing showed that 94 of the top 100 chlorpyrifos residue values were in imported peaches, and the highest 13 samples were all from Chile.

The major and growing contribution of imported fruits and vegetables in dietary risk is evident as well in the EPA-OIG results. Dimethoate Dietary Risk Index (DRI) scores in domestic grapes in 1996, 2000, and 2001 were respectively 0.1, 0.03, and 0.3. DRI values for dimethoate in imported grapes were 35.1, 42.9, and 21.6 in the same years.

The large increase in DRI scores per food tested for imports is worrisome and point to a rather marked increase in exposures and risk during the winter months. The shift in OP exposures from domestically grown to imported produce is caused in part by the way the FQPA has sought to reduce dietary pesticide exposures. The vast majority of FQPA-driven risk-reduction actions have entailed changes in U.S. pesticide product labels. The most common changes have been lower application rates, fewer applications, longer pre-harvest intervals, and other restrictions designed to lower farm worker risks. These label-driven changes in pesticide use patterns have in most cases not been accompanied by reductions in, or revocation of tolerances.

Label changes impact only U.S. pesticide use; tolerance changes impact farmers here and abroad, since they apply equally to domestic and imported foods. For this reason, U.S. farmers have been forced to adopt lower-risk use patterns, while growers outside the U.S. have been able to continue using older, higher-risk pesticides in ways no longer permitted in the U.S.

The only way for the FQPA -- and EPA actions -- to impact pesticide dietary exposures in foods imported in the U.S. is through lowering or revoking tolerances. Unfortunately, the EPA has lowered or revoked very few tolerances covering contemporary food uses of pesticides as a result of the FQPA.

F. Focus on Risk Drivers

Perspective can also be gained on the impact of EPA actions on pesticide dietary risk by focusing on regulatory actions targeting the riskiest pesticide-food combinations. The EPA, in its cumulative OP risk assessment, CU in its FQPA work, and the EPA-OIG analysis have produced similar lists of "risk-driver" pesticide-food combinations. The OIG analysis is the most recent and will be drawn on in this section. Any pesticide-food combination with a DRI value equal to or greater than 30 was considered a "risk driver."

In food grown domestically, 28 pesticide-crop combinations had DRI values greater than or equal to 30 in at least one year prior to 2000, plus one use of methyl parathion impacted by EPA regulations (processed green beans, DRI score of 22.6). The highest score was 799 for residues of methyl parathion in peaches in 1996.

Appendix B covers these 29 domestically grown food-pesticide combinations. For each pesticide food combination, a pre-FQPA DRI score is reported, along with the most recently available post-FQPA score. The changes in these scores can in several cases be attributed to EPA actions. Any reduction in DRI score for a food-pesticide combination for which the tolerance was revoked or voluntarily canceled, or reduced, is credited to "EPA action." Domestic food-pesticide combinations in the table are ranked by the percentage decrease in pre-FQPA risk levels, from the largest decrease to the least (or largest increase).

The impact of EPA actions in the course of implementing the FQPA on this set of 29 risk drivers is an important measure of the FQPA's effectiveness. EPA actions reduced the dietary risks associated with 10 of these 29 risk drivers. Risks stemming from seven of the 29 food-pesticide combinations increased from the pre-FQPA period to the most recent year the foods were tested by the PDP.

The EPA revoked the tolerances covering eight of these 29 risk-driver food uses, leading to a 100 percent decrease in risk for each use (after full implementation of the actions and time for food to clear market channels). Six involved the highly toxic OP, methyl or ethyl parathion.

Regulatory actions taken against methyl and ethyl parathion on six crops, and chlorpyrifos on three crops, accounted for 98 percent of the total risk reduction associated with EPA actions on these top 29 risk-driver food-pesticide combinations. Other risk drivers persist in children's foods that have yet to be impacted significantly by EPA actions. Pesticides at or near the top of this list include methamidophos, dimethoate, azinphos methyl, endosulfan, methomyl, carbaryl, and dicofol.

The same analysis was carried out on imported foods with DRI scores equal to or over 30 (see Appendix C). The results are similar. Parathion plus chlorpyrifos actions accounted for nearly all of the 1,390 DRI point reduction achieved in imported foods (99 percent).

G. Impacts of the Efforts to Reduce Children's Pesticide Exposures and Risk

The provisions of the FQPA apply to both residential and dietary routes of exposure, and

indeed, require the agency to carry out aggregate exposure and risk assessments. From the beginning of the implementation process, the EPA focused on dealing with a small number of residential uses of the OPs known to result in exposures well above the EPA's "level of concern."

Residential Uses of the OPs

The Environmental Protection Agency used the new authorities of the FQPA to act decisively to reduce residential uses of OP insecticides. By the end of 2000, all high-risk OP residential use patterns had been removed from the market, either by agency action or the imminent threat of action.

The EPA's actions on residential OP uses have already improved children's health. Research by a team led by Dr. Robin Whyatt has focused on the impacts of OP residential exposures during pregnancy and after birth among minority women in public housing projects in New York City. They found that chlorpyrifos exposures significantly reduced birth weight and length, as shown in Table 2.

They used regression analysis to assess whether there was a difference in the association between chlorpyrifos exposures and birth outcomes before and after the EPA's actions in the summer of 2000 that ended residential uses of chlorpyrifos. Prior to 2001, chlorpyrifos clearly impacted birth outcomes, but after the EPA actions taken in June 2000, levels of exposure declined and there was no longer a statistically significant association between insecticide exposures and birth outcomes, as shown

in Table 3 (Whyatt et al., 2004; Whyatt et al., 2005). This study provides the most encouraging evidence we know of linking an action driven by the FQPA to a significant reduction in prenatal and infant exposures and risk.

While the EPA's decisive actions on residential uses of OP insecticides were justified and welcomed, the agency has probably overestimated the portion of infant and child exposures to OPs associated with residential uses. It has taken strong actions against all residential uses of OPs, and only nine of some 60 food uses of OP insecticides with significant potential to contribute to children's risks.

Biomonitoring data lends further support to the conclusion that day-to-day dietary exposures to the OPs are more important than residential exposures in terms of explaining population-wide exposure patterns. Humans metabolize OPs quickly; metabolites found on a given day of monitoring likely reflect exposures in the preceding few days.

OP metabolite levels found in NHANES and other testing are relatively stable throughout the year and across regions (Adgate et al., 2001a; Centers for Disease Control and Prevention 2001). If residential uses were the major source of exposure, spikes in exposure levels would be expected in the spring and summer when pesticides are used more frequently in and around the home, and in southern and humid regions compared to northern, colder regions. No such spikes are evident in NHANES data or registrant submitted biomonitoring data on OPs such as chlorpyrifos.

Table 2. Difference in birth weight (g) and birth length (cm) by cord plasma OP exposure groups: Group 1 lowest exposure, Group 4 highest.

Birth Weights	CHLORPYRIFOS	CHLORPYRIFOS & DIAZINON
Group 1 vs group 2	39.2	-78.5
Group 1 vs group 3	-50.9	-33.1
Group 1 vs group 4	-150.1	-186.3
Birth Length	CHLORPYRIFOS	CHLORPYRIFOS & DIAZINON
Group 1 vs group 2	0.17	-0.06
Group 1 vs group 3	-0.21	-0.005
Group 1 vs group 4	-0.75	-0.8

Source: Whyatt et al., Prenatal insecticide exposures and birth weight and length among an urban minority cohort. *EHP*, July 12, 2004.

Table 3. Regression analysis of birth weight and length and organophosphate levels in umbilical cord plasma samples for infants born before and after 1 January 2001.

Born before Jan 1, 2001	BIRTH WEIGHT (g)	BIRTH LENGTH (cm)
Chlorpyrifos	-67.3	-0.43
Chlorpyrifos & Diazinon (sum)	-72.5	-0.46
Born after Jan 1, 2001	BIRTH WEIGHT (g)	BIRTH LENGTH (cm)
Chlorpyrifos	30.7	0.07
Chlorpyrifos & Diazinon (sum)	0.6	-0.07
Source: Whyatt et al., Prenatal insecticide exposures and birth weight and length among an urban minority cohort. <i>EHP</i> , July 12, 2004.		

Dietary Risks

The FQPA has brought about a modest to moderate reduction in pesticide dietary risks. Organophosphate insecticide urinary metabolite biomonitoring data collected by the Centers for Disease Control, through periodic NHANES surveys, supports this conclusion. NHANES surveys were carried out in 1988-1994, 1999-2000, and 2001-2002; the first survey was before the FQPA, the later two well after passage, and after the only major actions taken to date by the EPA targeting high-risk OPs (methyl parathion and chlorpyrifos).

Figure 6 shows trends in three metabolites corresponding to the herbicide 2,4-D, and the OPs methyl parathion and chlorpyrifos (Centers for Disease Control and Prevention 2001; Hill et al., 1995). All food uses of methyl parathion resulting in residues, according to PDP testing, were cancelled in 1999 and residues should have been out of the food supply by 2001. Likewise, major actions were taken in 2000 to end chlorpyrifos residential uses and reduce chlorpyrifos in the diet, yet the levels actually went up from 1999-2000 to 2001-2002, and have changed little since the 1988 sampling.

These data suggest that there are significant sources of exposure to these OPs other than those that the EPA identified as contributing most heavily to aggregate exposure. These might be additional crop uses in the U.S., or uses abroad, leading to exposures via imported foods.

Given the mandate of the FQPA, the EPA will almost certainly need to further reduce OP dietary

exposures. Thus far, the FQPA has sharply reduced less than a dozen high-risk OP uses in the U.S., and restricted a few dozen more, but has left most uses untouched abroad. In the absence of tolerance revocations and reductions, the FQPA may simply further shift risks from U.S. grown produce to food imported from abroad.

Shift in Risk to Imports

Changing patterns of residues in domestic versus imported foods, and analyses of the distribution of OP dietary risks, show a dramatic shift of risk from fresh fruits and vegetables grown in the U.S. to those imported from abroad. This shift has distinct economic and trade ramifications.

The costs of pest management systems in the U.S. have risen, as farmers have dropped high-risk but relatively cheap OPs, and adopted newer, lower-risk but more expensive pesticides and Integrated Pest Management systems. Some, and perhaps most growers in some countries are still using older, high-risk and low-cost OPs and carbamates in ways no longer allowed in the U.S. A number of studies have shown that fruit and vegetable pest management costs in the U.S. often exceed costs in Mexico, Central, and South America by several hundred dollars per acre. Farmers may be receiving lower prices and losing market share as a result of these FQPA-driven differences in pest management costs, and U.S. consumers may become more reliant on higher-risk imported foods.

In the three foods impacted by actions on chlorpyrifos and the six crops impacted by

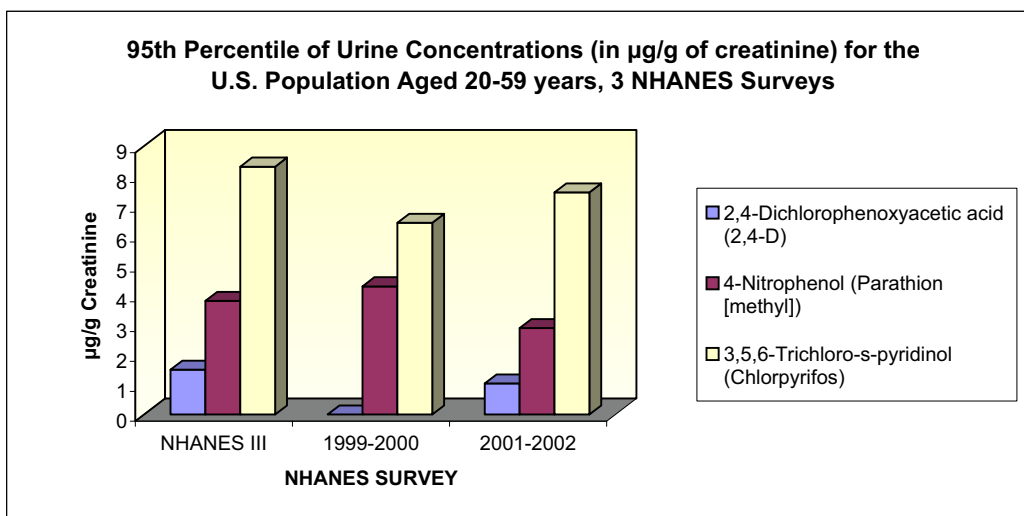


Figure 6. 95th percentile of urine concentrations (µg/g creatinine corrected) for the U.S. population age 20-59 years, three NHANES surveys

revocation of parathion tolerances, U.S. farmers have typically replaced these high-risk OPs with reduced-risk insecticides and biopesticides. In particular, imidacloprid (Admire) and other nicotiny insecticides, spinosad, improved formulations of *Bacillus thuriangiensis* (Bt), and several new-generation insect growth regulators (IGRs), have replaced the higher-risk OPs impacted by EPA regulatory actions. Whether this remains the case deserves close monitoring by the EPA, and will eventually become evident in PDP test results.

The lack of a significant number of OP tolerance revocations and reductions, however, increases the chances that new risk drivers will periodically emerge in children's foods, especially in imported foods. This risk is especially great during winter months when a significant share of fresh produce is imported.

H. More Cumulative Risk Challenges Ahead

The EPA has completed a cumulative risk assessment (CRA) on just one family of chemistry – the OPs. A CRA of the carbamates is nearly complete, but no major regulatory actions have been taken as a result of the carbamate CRA. Several other families of chemistry await CRAs, including the triazine and acetanilide herbicides, the EBDC fungicides, and the synthetic pyrethroid insecticides.

The agency will have to decide whether to conduct a cumulative risk assessment of the OPs and carbamates together, given that both families of chemistry work through a common mode of action.

A last point deserves emphasis. The EPA carried out the cumulative risk assessment of the OPs focusing on cholinesterase inhibition because it had relatively good data on this endpoint for most OPs, and it is indeed a common mechanism shared by these insecticides. Cholinesterase inhibition, while an important and reliable indicator of neurotoxicity, is not the biological impact of gravest concern associated with OP exposures.

Most toxicologists are far more concerned about the developmental impacts of the OPs, yet the agency lacks the data and methods to conduct a cumulative risk assessment based on neurological, immune, or reproductive developmental impacts. When such assessments are completed, it is likely that additional restrictions on OP use and exposures will be necessary to meet the FQPA's "reasonable certainty of no harm" standard.

In the past decade some progress has been made in reducing pesticide dietary risks. Emerging science strongly supports the need for more comprehensive and aggressive steps to curtail children's dietary exposures to pesticides.

The pest management tools accessible to farmers, and the regulatory authorities and mandate governing EPA actions, seem fully up to the task, yet resistance to change remains strong. Over time new and more compelling science will highlight the need for additional, specific risk reduction measures. We hope this information will reach both consumers and regulators and trigger a renewed and focused effort to eliminate significant risks in foods commonly consumed by infants and children.

Appendix A. Dietary Risk Methodology Used in the Benbrook OIG Report

The basic unit of measure used to track pesticide dietary risks in the EPA-OIG report is called the “Dietary Risk Index” (DRI). DRI values or scores are calculated for each pesticide-food combination covered in annual PDP testing. For a given food and year, DRI values for each pesticide found in the food are added together, to form an aggregate, food-level DRI score; aggregate pesticide DRI scores can also be calculated by adding DRI values from all foods a given pesticide is found in.

Single-food and aggregate DRI scores are calculated for three sets of residue data: food grown, harvested, and processed in the U.S. (domestic production); residues in food that is imported into the U.S.; and all PDP samples (domestic plus imported samples, plus samples of unknown origin). Trends over time in aggregate food-level DRI scores provide insights into changes in overall risk levels, as well as the crops and pesticides contributing most significantly to risk.

The basic formula to calculate the DRI score for a given pesticide-food combination is –

$$\text{DRI} = (\text{“Percent Positive”}) \times (\text{“Chronic Risk Share”})$$

Where:

- “Percent Positive” is the number of samples of a given food found to contain a quantifiable level of a given pesticide residue, divided by the total number of samples of the food tested for that residue; and
- “Chronic Risk Share” is the level of risk associated with the residues of a pesticide found in a food, taking into account the pesticide’s toxicity, the amount of food typically eaten by children, and the mean of the residues found in positive samples.

The “Percent Positive” variable is calculated from PDP data. For each pesticide-food combination, there are up to three “Percent Positive” values: one representing the results for domestic samples, one for imports, and one for all samples combined.

DRI values can be calculated based on acute Reference Doses (aRfD) and acute Population Adjusted Doses (aPAD), as well as chronic Reference Doses (cRfD) and chronic PADs (cPAD). The analysis of dietary risk trends in the EPA-OIG report is based on chronic risks, because the EPA has not established acute Reference Doses for a majority of pesticides.

Chronic Risk Share

The “Chronic Risk Share” (CRS) is designed to help answer a key question: “How risky are the pesticide residues found in a given food, or across all foods?” The “Chronic Risk Share” is a measure of the degree to which the residues found in the food, as reported in PDP results, fills up the pesticide’s “risk cup” for a person of known weight.

The EPA introduced the “risk cup” concept to help explain the impact of the provisions of the FQPA on allowable levels of exposure to pesticides. The “risk cup” is a graphical representation of the acceptable amount of exposure to a given pesticide for a person of known weight. The size of the risk cup is typically reported in milligrams of pesticide per day.

The “Chronic Risk Share” for a given pesticide-food combination is calculated as follows –

$$\text{Chronic Risk Share} = \frac{(\text{“Projected 99th Residue Level”})}{(\text{“Single-Food cRfC”})}$$

The “Projected 99th Residue Level” (PRL₉₉) is an estimate of the 99th percentile level of the distribution of residues of that chemical in that food, ranked from the highest to lowest. To estimate PRL₉₉ values, we analyzed the differences in PDP residue levels for 53 pesticide-food combinations at the 99.9th, 99th, 95th, and mean levels. The average difference between the 99th residue and the mean of the positives was about 7. We estimated PRL₉₉ levels for all pesticide-food combinations by multiplying the mean residue level by 7.

The PRL₉₉ level of exposure is modestly less conservative than the EPA’s science policy for dietary risk assessment that calls for the “threshold of regulation” to be set at the 99.9th percentile of the distribution of risks. Pesticide-food combinations resulting in risks that exceed the applicable EPA Reference Dose or PAD at the 99.9th level of the distribution are said to exceed the agency’s “level of concern,” and may trigger risk mitigation efforts.

The second component used to calculate the CRS is the pesticide’s single-food chronic Reference Concentration (cRfC). Four variables are needed to calculate a single-food cRfC for a child of known weight – the average amount of food consumed by the child, the child’s weight, the toxicity of the pesticide, and the magnitude of exposures from other foods, beverages, or pesticide uses around the home, schools, or in other residential settings. A single-food cRfC is an estimate of the concentration of a pesticide that can be present in a serving of a given food, without exceeding the person’s chronic PAD.

In cases in which the PRL₉₉ exceeds the applicable single-food chronic Reference Concentration, the value of the CRS will be greater than 1. In such cases, a small portion of the people consuming the food in a given day are likely to receive a dose of the pesticide above the level that the EPA regards as acceptable from that food alone. The smaller the value of the CRS, the less worrisome the dietary risks stemming from the residues present in a given food.

Single-Food Chronic Reference Concentrations

The single-food chronic Reference Concentration, or cRfC_{sf}, is an estimate of the maximum level of a pesticide that can be present in a given food without violating the FQPA’s basic “reasonable certainty of no harm” standard. This key concept is useful in tracking changes in pesticide dietary risks, as well as when setting the maximum levels for “safe” pesticide tolerances in food as eaten.

A cRfC_{sf} for a given pesticide will change as a function of the weight of a child and the amount of a specific food that the child consumes during a day. In analyzing changes over time in pesticide dietary risks one must realize that assumptions used to calculate cRfC_{sf} levels are less important than using the same assumptions across all foods.

The formula to calculate a cRfC for all foods and routes of exposure is:

$$\text{cRfC (mg/kg)} = \frac{\text{Weight of Child (kg)} \times \text{cPAD (mg/kg/day)}}{\text{Serving Size Food}_y \text{ (kg/day)}}$$

The weight of the child used in this report to calculate cRfC values is 16 kilograms, the weight roughly corresponding to mid-range growth for a 4-year-old male, as reported in the Centers for Disease Control Growth Chart.

The EPA sets pesticide cPADs based on animal experiments, after applying a set of safety factors to the “No Observable Adverse Effect Level” (NOAEL), for the most sensitive biological impact considered relevant in assessing a pesticide’s toxicity.

In order to track dietary risks using a methodology grounded in the EPA's FQPA science policies, we estimated the serving size for each food at the 95th percentile of the food distribution curve. The combination of food consumption at the 95th percentile level, and pesticide residues at the 99th level produces estimates of risk comparable to the 99.9th level that the EPA uses as the threshold for regulation.

Children are typically exposed to a given pesticide through more than one food and beverage. Pesticides are also sometimes used in and around the home, schools, or play areas, leading to non-food routes of exposure. The FQPA requires the EPA to set tolerance levels, and regulate pesticides such that total aggregate exposures from all foods, beverages, and other routes fit within each pesticide's "risk cup," thereby meeting the statute's basic reasonable certainty of no harm" standard.

A large amount of data and considerable analytical work is required to rigorously estimate single-food cRfCs for all pesticides. Based on past analyses of PDP residue levels and food consumption survey data, we estimated that most pesticides appear in three to about a dozen foods commonly consumed by children. Perhaps one-quarter of pesticides is also found in drinking water and residential environments, but resulting exposure levels vary a great deal, and sometimes dwarf exposures from food.

We approximated the share of an "all-routes-of-exposure" cRfC that can be taken up by a single food by dividing the cRfC by 10. This value was recommended previously to the EPA in October 13, 2000 Consumer Union comments on the agency's chlorpyrifos risk mitigation plan. CU recommended that the EPA not allow any single food use of a pesticide to account for more than 10 percent of the pesticide's risk cup, at least not until the EPA completed its cumulative risk assessment of the organophosphates and had taken all regulatory actions needed to meet the FQPA's "reasonable certainty of no harm" standard.

APPENDIX B

Impact of EPA Actions on Risk Driver Pesticide-Food Combinations (Domestic), Ranked by Percentage Change in Dietary Risk Index Levels from the Pre-FQPA Period						
Commodity	Pesticide	DRI Score	Year	Change in DRI Score	Pre-FQPA Tolerance	Current Tolerance
Grapes	Parathion methyl	0	2001	-100%	1	revoked
		329.1	1994			
Spinach, Processed	Parathion ethyl	0	1999	-100%	1	revoked
		88.2	1998			
Peaches	Parathion methyl	1.6	2001	-100%	1	revoked
		799.4	1996			
Pears	Parathion methyl	0	2003	-100%	1	revoked
		78.1	1997			
Apples	Parathion methyl	0.7	2001	-99%	1	revoked
		52	1996			
Apples	Chlorpyrifos	3.6	2002	-98%	1.5	0.01
		207.3	1996			
Strawberries	Vinclozolin	4.4	2000	-93%	10	10
		65.7	1998			
Wheat flour	Chlorpyrifos methyl	13.9	2003	-91%	6	voluntary cancellation
		149.2	1996			
Grapes	Dicofol p,p'	10.1	2000	-88%	5	5
		82.7	1996			
Strawberries	Dicofol p,p'	13.4	2000	-80%	5	5
		67.3	1998			
Tomatoes	Methamidophos	34.9	2003	-76%	1	1
		143.4	1996			
Cucumbers	Dieldrin	33.6	2003	-70-	0.1	0.1
		111.3	1999			
Sweet Bell Peppers	Chlorpyrifos	20.7	2003	-68%	1	1
		65	1999			
Pears	Azinphos methyl	19.6	2003	-67%	2	1.5
		58.6	1997			
Tomatoes	Chlorpyrifos	13.2	2003	-64%	0.5	revoked
		36.8	1997			
Winter squash	Dieldrin	77.8	1999	-57%	0.1	0.1
		179.3	1997			
Cucumbers	Methamidophos	13.4	2003	-55%	1	1
		29.8	1999			
Sweet Bell Peppers	Methamidophos	60.9	2003	-49%	1	1
		119.1	1999			
Green Beans	Endosulfans or Endsulfan Sulfate	20	2001	-47%	2	2
		37.6	1995			
Strawberries, processed	Dicofol p,p'	22.8	2000	-37%	5	5
		36.1	1998			
Winter squash, processed	Dieldrin	228.5	1999	-36%	0.1	0.1
		354.4	1997			
Green Beans	Dimethoate	20.6	2001	-31%	2	2
		30	1994			

Continued...Impact of EPA Actions on Risk Driver Pesticide-Food Combinations (Domestic), Ranked by Percentage Change in Dietary Risk Index Levels from the Pre-FQPA Period

Commodity	Pesticide	DRI Score	Year	Change in DRI Score	Pre-FQPA Tolerance	Current Tolerance
Green Beans	Acephate	55.5	2001	9%	3	3
		51	2004			
Green Beans, Processing	Methamidophos	98.7	1998	11%	3	Acephate tolerance (all residues are associated with acephate)
		89.1	1996			
Green Beans	Methamidophos	205.1	2001	23%	1	Acephate tolerance (all residues are associated with acephate)
		166.3	1995		3	
Celery	Acephate	36.5	2002	25%	10	10
		29.2	1994			
Strawberries, processed	Vinclozolin	31.6	2000	76%	10	10
		17.9	1998			
Potatoes	Chlorpropham	61.1	2002	114%	50	50
		28.5	1995			
Green Beans, Processing	Parathion methyl	49.5	1998	119%	1	revoked
		22.6	1996			
Peaches	Dicofol p,p'	33.8	2001	4131%	10	10
		0.8	1996			
TOTAL EPA ACTIONS	1,649.0	%				
PARATHIONS	1,369.4	83%				
CHLORPYRIFOS	240.5	15%				
PARA & CHLOR	1,610.0	98%				

Appendix C. Impact of EPA Actions on Risk Driver Pesticide-Food Combinations Ranked by Percentage Change in Dietary Risk Index Levels from the Pre-FQPA Period (Imported Samples)

Commodity	Pesticide	DRI Score	Year	Change in DRI Score	Pre-FQPA Tolerance	Current Tolerance
Green Beans, Processed	Parathion methyl	0	2003	-100%	1	revoked
		200.6	1997			
Broccoli	Mevinphos	0	2002	-100%	1	1
		95	1994			
Grapes	Mevinphos	0	2001	-100%	0.5	0.5
		34.5	1994			
Apples	Chlorpyrifos	13.9	2002	-97%	1.5	0.01
		454.9	1996			
Tomatoes	Chlorpyrifos	68.8	2003	-85%	0.5	revoked
		451.8	1996			
Apple Juice	Dimethoate	11.1	1998	-83%	2	2
		65	1996			
Sweet Bell Peppers	Methamidophos	92.3	2003	-72%	1	1
		327.8	1999			
Winter Squash	Dieldrin	1.1	1999	-68%	0.1	0.1
		3.4	1997			
Cucumbers	Endosulfan I	15	2003	-55%	2	2
		33.5	1999			
Grapes	Dimethoate	21.6	2001	-38%	1	1
		35.1	1996			
Pears	Azinphos methyl	30.7	1999	-33%	2	1.5
		45.8	1997			
Cucumbers	Methamidophos	179.8	2003	-32%	1	1
		264.4	1999			
Green Beans, Processed	Methamidophos	27.6	2003	-10%	3	Acephate tolerance (all residues are assoc. with acephate)
		30.5	1997			
Tomatoes	Methamidophos	41.1	2003	-8%	1	1
		48	1996			
Sweet Bell Peppers	Chlorpyrifos	586.6	2003	-2%	1	1
		595.6	1999			
Celery	Acephate	16.6	2002	8%	3	3
		15.4	1994			
Peaches	Dicofol p,p'	22.3	2002	18%	10	10
		18.9	1996			
Lettuce	Endsulfan I	3.2	2001	100%	2	2
		0	1994			
Strawberries, Processed	Vinclozolin	73.9	2000	100%	10	10
		0	1998			
Spinach, Processed	Dimethoate	164.2	1999	100%	2	2
		0	1998			
Broccoli	Methamidophos	107.9	2001	100%	1	1
		0	1994			
Celery	Methamidophos	104.3	2002	225%	1	1
		32.1	2001			
Pears	Dicofol p,p'	120.6	1999	324%	5	5
		28.5	1998			
Cantaloupe	Methamidophos	92.7	2000	409%	0.5	0.5
		18.2	1999			
Strawberries	Endosulfan I	71.3	1999	414%	2	2
		13.9	1998			
Potatoes	Chlorpropham	14.5	2002	1971%	50	50
		0.7	1995			
Peaches	Methamidophos	31.1	2002	11419%	NT - violation	0.02
		0.3	1996			
TOTAL EPA ACTION	1,039.7	%				
PARATHIONS	200.6	19%				
CHLORPYRIFOS	824.0	79%				
PARA & CHLOR	1,024.6	99%				

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