OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Evaluation Report

Measuring the Impact of the Food Quality Protection Act: Challenges and Opportunities

Report No. 2006-P-00028

August 1, 2006

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Abbreviations

EPA	U.S. Environmental Protection Agency
FQPA	Food Quality Protection Act
GAO	Government Accountability Office
OIG	Office of Inspector General
OPP	Office of Pesticide Programs
USDA	U.S. Department of Agriculture

Cover photo: The Food Quality Protection Act emphasizes the need to protect children from pesticides (EPA OIG photo).

U.S. Environmental Protection Agency
Office of Inspector General

2006-P-00028
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At a Glance

Catalyst for Improving the Environment

Why We Did This Review

We initiated this review to determine the ability of the U.S. Environmental Protection Agency's (EPA's) Office of Pesticide Programs (OPP) to measure its performance in meeting the mandates of the Food Quality Protection Act (FQPA). We sought to determine the strengths and weaknesses of OPP's current measuring system, how OPP can use existing data to measure, and what impact FQPA had on mitigating dietary pesticide exposure risk on children's health. This is the third in a series of three reports on FQPA.

Background

The goal of EPA's pesticide program is to protect public health and the environment by ensuring pesticides are used safely. FQPA changed the way OPP regulates pesticides and emphasizes protecting children's health.

For further information, contact our Office of Congressional and Public Liaison at (202) 566-2391.

To view the full report, click on the following link:
www.epa.gov/oig/reports/2006/20060801-2006-P-00028.pdf

To view a supplemental report with additional details, click on:
www.epa.gov/oig/reports/2006/20060801-2006-P-00028A.pdf

Measuring the Impact of the Food Quality Protection Act: Challenges and Opportunities

What We Found

Although EPA has made progress in implementing the requirements of the FQPA, we found that OPP has primarily measured its success and the impact of FQPA by adherence to its reregistration schedule rather than by reductions in risk to children's health. The measures used by OPP generally indicate actions taken, instead of environmental or human health outcomes achieved. OPP lacks outcome measures to assess the specific impact of those actions on the health of children and others. OPP has recently taken steps to develop outcome measures, but significant challenges remain.

By integrating existing data into a suite of performance measures, OPP can better track the effectiveness of regulatory decisions and program performance. We identified several pools of quantitative data available for use as a suite of performance indicators, but coordination efforts will be needed. OPP can better utilize a number of data and measurement sources, including the National Health and Nutrition Examination Survey and the U.S. Department of Agriculture's Pesticide Data Program, to track health-based indicators of children's health risks.

EPA can measure the impact of FQPA on children's health more efficiently through the examination of pesticide exposure data, and changes in usage patterns, substitutions, and import trends. We used the U.S. Department of Agriculture's Pesticide Data Program data to illustrate dietary risk changes since the passage of FQPA in toxicity risks on the foods commonly consumed by children.

What We Recommend

We recommend that OPP work to move away from primarily using outputs as performance measures, and implement a suite of output and outcome measures to assess the human health and environmental impacts of its work. We also recommend that OPP pursue revision of EPA's goal structure as appropriate, and work with other EPA program offices and other Federal agencies to obtain needed data. EPA generally agreed with the recommendations, and expressed its appreciation for our findings. We made changes where appropriate.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

August 1, 2006

MEMORANDUM

SUBJECT: Measuring the Impact of the Food Quality Protection Act: Challenges and Opportunities
Report No. 2006-P-00028

TO: Jim Jones
Director, Office of Pesticide Programs

Lyons Gray
Chief Financial Officer

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established resolution procedures.

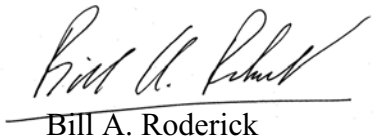
The estimated cost of this report – calculated by multiplying the project's staff days by the applicable daily full cost billing rates in effect at the time – is $227,099.

Action Required

In accordance with EPA Manual 2750, you are required to provide a written response to this report within 90 calendar days. You should include a corrective actions plan for agreed upon actions, including milestone dates. We have no objections to the further release of this report to the public. This report will be available at http://www.epa.gov/oig.

If you or your staff has any questions, please contact me at (202) 566-0847 or roderick.bill@epa.gov, or Jeffrey Harris, Product Line Director for Cross Media Issues, at (202) 566-0831 or harris.jeffrey@epa.gov.

Sincerely,



Bill A. Roderick
Acting Inspector General

cc: James B. Gulliford
Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances

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Chapter 1
Introduction

Purpose

We initiated this review to evaluate the U.S. Environmental Protection Agency's (EPA's) activities to implement the Food Quality Protection Act (FQPA) of 1996. Our overall objective was to determine the impact of FQPA on Agency practices, data requirements, and children's health. The primary goal of FQPA is to protect children and infants from pesticide exposures. In this report, our primary objective was to evaluate the effectiveness of EPA's Office of Pesticide Programs (OPP) in measuring the overall impact of FQPA implementation activities. We specifically sought to determine:

- What are the strengths and weaknesses of OPP's current measurement system in tracking FQPA objectives, and how could it be improved, if necessary?
- What existing data can OPP use to assess its performance under FQPA and measure the impact of its regulatory actions?
- What impact did FQPA have on mitigating dietary pesticide exposure risk and on children's health?

Background

Congress unanimously passed the FQPA in 1996, due in large part to a 1993 National Academy of Sciences report, *Pesticides in the Diets of Infants and Children*. According to this report, the then-current scientific and regulatory approaches did not adequately protect infants and children from pesticides. Children are uniquely susceptible to the health threats posed by pesticides, in both household chemicals and food. Children generally consume more fresh produce and drink more water per pound of body weight than adults. Additionally, a child's exposure to pesticides can occur as early as the prenatal phase, or during infancy through breast-feeding. Children have higher rates of metabolism, less mature immune systems, unique diets, and distinct patterns of activity and behavior when compared with adults.

The Government Performance and Results Act of 1993 requires Federal agencies, including EPA, to prepare performance plans containing annual performance goals and measures to help move them toward managing for results. Performance measurement is the monitoring and reporting of program accomplishments, particularly progress toward pre-established goals. Performance measures may

address the type of program activities conducted, the direct products and services delivered by a program (outputs), and the results of those products and services (outcomes). Effective performance measurement enables an agency to establish baselines; identify and prioritize problems; and evaluate, manage, and improve programs. Table 1.1 further defines performance measurement terms.

Table 1.1: Performance Measurement Terminology

Term	Definition
Inputs	Personnel, funds, and other resources that contribute to an activity
Outputs	Quantitative or qualitative measures of activities, work products, or actions
Intermediate Outcomes	Changes in knowledge, behavior, or conditions that result from program activities and are needed to achieve the end outcome
End Outcomes	The ultimate outcomes of program activities – the results compared to their intended purpose

EPA's strategic plan outlines the Agency's five long-term goals and guides in establishing the annual goals that must be met along the way. To fulfill its five strategic goals, the plan includes a series of more specific goals in the form of objectives and sub-objectives. Each of these objectives has associated performance measures designed to demonstrate progress in achieving the objective and, eventually, the strategic goal. The annual performance plan defines the Agency's budget and associated goals and objectives in greater detail and ties the annual budget to the 5-year strategic plan.

The mission of OPP is to protect human health and safeguard the environment from unreasonable adverse effects resulting from the use of pesticides. OPP is responsible in part for implementing the FQPA. To successfully implement FQPA, OPP needs to use new tools to reduce pesticide exposures and resultant risks for children. OPP is responsible for using performance measures and goals to assess the impact of its actions.

Scope and Methodology

We generally performed our evaluation in accordance with *Government Auditing Standards*, issued by the Comptroller General of the United States. We performed our field work from July 2005 through January 2006.

To determine the strengths and weaknesses of OPP's current FQPA-related measurement system, we reviewed internal OPP documents, EPA Office of the Chief Financial Officer reports and plans, and Office of Management and Budget documents. We reviewed EPA's *2003 – 2008 Strategic Plan: Direction for the Future,* fiscal 2004 and 2005 annual performance plans, and the Agency's fiscal 2004 and 2005 annual reports. We interviewed internal program staff, and

internal and external stakeholders. We reviewed reports issued by the Government Accountability Office (GAO). We reviewed Florida State University's Program for Environmental Policy and Planning Systems' Chemical and Pesticide Results Measures project, a cooperative agreement with OPP, and interviewed the author of a report prepared as a result of the project. We also interviewed other members of academia.

To determine what additional data sources and measures OPP could use and other ways it can use existing data sources, we consulted the U.S. Department of Agriculture, U.S. Department of Health and Human Services, Office of Management and Budget, and EPA's Office of the Chief Financial Officer.

In assessing the overall impact of OPP's actions on children's health, we interviewed internal program staff, and internal and external stakeholders, to identify measures, additional data, and trends in children's health. We reviewed other entities' research on potential human health indicators related to pesticide exposures, dietary risk, and reductions in risk due to EPA action. We conducted an analysis of publicly available toxicological and residue data supporting EPA dietary risk assessments to assess the impact of FQPA on dietary pesticide risks from 1994 through 2003.[1] A detailed discussion of the methodology for this analysis, which can be used by OPP to perform its own analyses, is in a supplemental report.

Our review focused on existing data and interviews, and we did not examine internal controls. We evaluated OPP's compliance with the Government Performance and Results Act, FQPA, and other regulations as appropriate.

Prior Reviews

This report is the last in a series of three EPA Office of Inspector General (OIG) reports on the Agency's FQPA implementation efforts. The prior two reports are:

- EPA OIG Report No. 2006-P-00009, *Opportunities to Improve Data Quality and Children's Health through the Food Quality Protection Act,* January 10, 2006
- EPA OIG Report No. 2006-P-00003, *Changes Needed to Improve Public Confidence in EPA's Implementation of the Food Quality Protection Act,* October 19, 2005

In addition, we reviewed the following GAO reports that addressed performance measures:

[1] Some of the analysis work was conducted through a contract with Benbrook Consulting Services, Sandpoint, Idaho.

- GAO-05-52, *Environmental Indicators: Better Coordination Is Needed to Develop Environmental Indicator Sets That Inform Decisions,* November 17, 2004
- GAO-02-372, *Performance Reporting: Few Agencies Reported on the Completeness and Reliability of Performance Data,* April 26, 2002
- GAO Letter Report B-285312, *Managing for Results: Assessing the Quality of Program Performance Data,* May 25, 2000
- GAO/RCED-00-77, *Managing for Results: EPA Faces Challenges in Developing Results-Oriented Performance Goals and Measures,* April 2000

Further, we reviewed a report issued by the Florida State University's Program for Environmental Policy and Planning Systems in February 2003, *Chemical and Pesticide Results Measures II*. The report was based on a joint effort by EPA and the university to develop a national set of chemical, pesticide, and pollution prevention indicators to describe and understand environmental trends and conditions concerning chemical and pesticide issues.

We also reviewed reports issued by the Office of Management and Budget on its Program Assessment Rating Tool assessments of EPA. The Office gave OPP's pesticide registration and reregistration programs "results not demonstrated" ratings in fiscal 2003, but improved the rating for the registration program to "adequate" in fiscal 2004.

Results of Review

OPP needs to move to a better mix of output and outcome measures to assess its performance in achieving FQPA's mandate of protecting children from pesticide exposure risks. Although EPA has made progress implementing the requirements of FQPA, we found that OPP has primarily measured its success and the impact of FQPA by adherence to its reregistration schedule rather than by improvements in children's health. While OPP has recently taken steps to develop more outcome measures, significant challenges remain. We identified opportunities for OPP to utilize existing data in different ways to track the effectiveness of its pesticide regulatory decisions and program performance. We conducted an analysis of the dietary pesticide residue data from the U.S. Department of Agriculture's Pesticide Data Program and found that EPA's regulatory actions had a significant impact in reducing pesticide exposure risk on domestic foods commonly eaten by children. The Agency concurred with our recommendations. We summarized the comments and provided our evaluations at the end of each chapter. The full text of EPA's memorandum and comments is in Appendix A.

Chapter 2
Improvements Needed in OPP's Measurement System

OPP launched an internal workgroup in May 2005 to develop better measures, but none of the proposed measures have been implemented. OPP faces a number of challenges in creating effective measures, including: the complexity of environmental problems, external factors, cost, and an historical reliance on output measures. Since 1996, OPP has tracked success in meeting statutory deadlines and progress toward mandated FQPA goals. FQPA required OPP to complete the reassessment of all 9,721 food-related pesticide tolerances by August 2006. While important and required, these output measures, which comprise the majority of OPP's performance measurement system, do not measure impact. Because it lacks measures on the impact of actions on the health of infants, children, and the overall human population, OPP cannot state the impact of its FQPA efforts. Several opportunities for OPP to improve performance measurement are discussed in this chapter and Chapters 3 and 4.

OPP's Current Measurement System Focuses on Outputs

A good performance measurement and reporting system ensures transparency and holds an organization accountable. OPP adopted transparency and accountability as goals, and further noted that accountability is paramount to the development of effective performance measures.

OPP uses the graphic in Figure 2.1 to illustrate its view on the importance of performance measures as accountability tools for a number of purposes. The measures ensure that OPP provides stakeholders and the Agency with a cohesive display of the program. OPP intends to use performance measures in most if not all of the areas indicated in the figure. OPP uses performance measures as part of EPA's strategic planning. In the Agency's overall structure, OPP's FQPA-related work falls under Goal 4: Healthy Communities and Ecosystems.

Figure 2.1: Performance Measures for Accountability

Source: OPP

Output measures were important to OPP during FQPA implementation in terms of meeting congressionally mandated deadlines and timeframes. While output

measures are needed, they comprised all but two of OPP's performance measures in the Fiscal Year 2005 annual report. The lack of outcome-based measures impedes OPP's ability to assess the impact of its actions.

For Fiscal Year 2005, OPP used the following output measures to assess programs:

- Cumulative number of safer chemicals/biopesticides registered.
- Cumulative percentage of the 9,721 tolerances required to be reassessed over 10 years that have already been reassessed.
- Cumulative number of new uses.
- Number of inert ingredients in pesticide products reregistered.
- Cumulative number of new chemicals registered.
- Cumulative percentage of Reregistration Eligibility Decisions completed.
- Percentage of tolerance reassessments issued for the "Top 20" foods eaten by children.
- Children's exposure data and tools for assessing aggregate exposure to residential use pesticides.
- Number of product reregistrations.

One of the strengths of OPP's current output measures is that the majority are based on actual counts, not on modeling or predictions. Staff can easily collect, compute and analyze the data. However, one of the major weaknesses is that OPP staff and other data users cannot draw conclusions, trends, or significant analyses from the measures about the impact of actions. While output measures are important as an internal program management tool, their value in illustrating actual programmatic success and impact is severely limited. Counts of registration and reregistration numbers alone do not provide evidence that children's health benefited from a reduction in pesticide exposure risk.

OPP's two outcome-based measures for FY 2005 were:

1. The reduction of detections on a core set of 19 foods eaten by children relative to detection levels for those foods reported in 1994-1996; and
2. The percentage of acre treatments with reduced risk pesticides.

Both were low-level outcomes in the hierarchy of measures,[2] but nonetheless provided a clearer picture to OPP of the impact of its FQPA-related actions than the output structure.

[2] Performance measures can be categorized along a "hierarchy" of measures. Levels 1 and 2 measure administrative actions and program activities (outputs), while levels 3 through 5 represent intermediate outcomes and level 6 represents long-term outcomes. As the measures progress from levels 3 to 6, the association of the indicator to environmental outcomes strengthens. While level 6 outcomes are important, they are less feasible for measurement than levels 3 through 5.

OPP staff said the greatest outcome from implementing FQPA is the reduction in household poisonings. By removing household uses of many toxic pesticides, OPP reduced the potential for children's exposure to those pesticides. However, OPP does not have measures to show reduction in household poisonings or use patterns. In its 2004 annual report, OPP cited two success stories that lacked measures with which to capture their impact. One involved the elimination of a product (thiram) from almost all residential uses. OPP also noted that EPA pesticide reregistration decisions in response to FQPA resulted in removal of 15 million to 20 million pounds of organophosphates from use in and around homes annually. These successes, however, cannot be inferred by the general public and stakeholders from any of OPP's performance measures.

Outcome Measures under Development

In May 2005, OPP established an internal workgroup to develop results indicators for its program as a whole. OPP has had one full time person working on performance measures since the inception of the workgroup, but other staff members have devoted significant amounts of time in developing the initiative. The workgroup has proposed measures (see Appendix B), but these measures have not yet been implemented. Under this performance measurement project, OPP has identified the following overall strategic measures for reducing risk to the general public:

- Reduce the number of acute poisoning incidents from pesticides in and around the home.
- Reduce the level of currently registered pesticides in the general population.
- Reduce pesticide residues in the 20 foods most commonly eaten by children using Pesticide Data Program residue data.

OPP Faces Challenges in Creating Effective Performance Measures

OPP faces a number of challenges in creating effective, outcome-based performance measures. These include: the complexity of environmental problems, external factors, data housed in other Federal agencies, the expense of collecting new human health data, and the historical reliance of the organization on output-based measures.

OPP, like EPA as a whole, faces significant performance measurement challenges related to environmental problems. Data on environmental conditions and health effects of pollutants are limited. Further, there are difficulties in linking a program's activities and the resulting changes in the environment. Numerous factors beyond EPA's control, such as technological change and socioeconomic factors, play a role. Although EPA has volumes of data on individual pesticides, OPP is often prohibited from releasing it due to confidential business information.

OPP needs to obtain a great deal of its data from other Federal agencies, and thus is reliant on the type of data those other agencies collect. The U.S. Department of Agriculture (USDA) provides data on food consumption, food commodity, and pesticide residue through such databases as the Food Commodity Intake Database. FQPA contains specific provisions for cooperative activities between EPA and USDA. Since 1999, USDA integrated its food intake survey with another large survey – the National Health and Nutrition Examination Survey – conducted by the U.S. Department of Health and Human Services. The main data source for dietary residues is the monitoring study conducted by the Pesticide Data Program at the USDA Agricultural Marketing Service. This program has generated extensive pesticide residue data on over 50 foods eaten daily, including data on pesticide residues in fruits, vegetables, grains, dairy products, and meats. OPP recognizes that it can obtain valuable data from such sources as the National Health and Nutrition and Examination Survey and Pesticide Data Program, and it needs to maximize its opportunities to obtain and use this information.

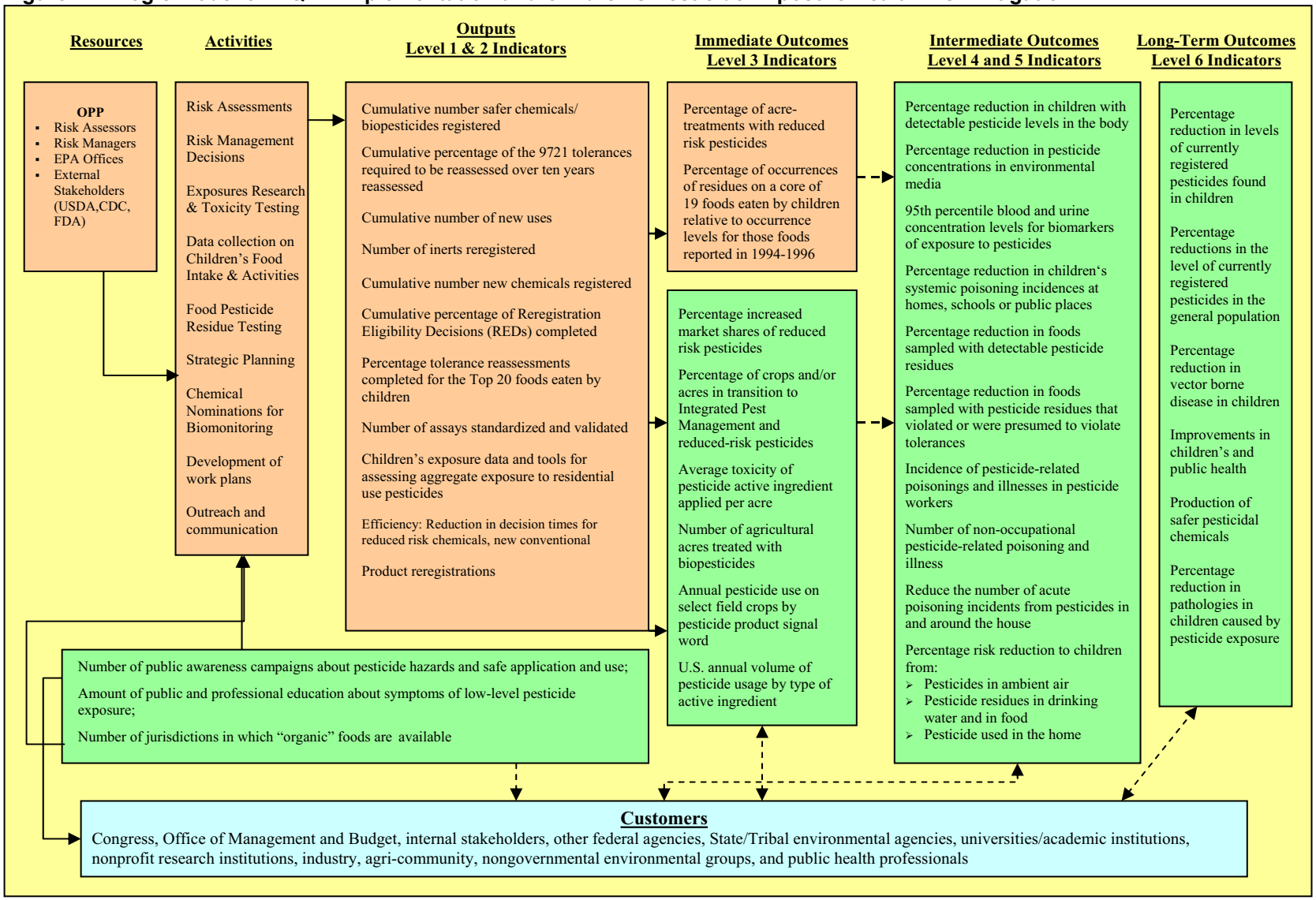
OPP's mission is not one of zero risk or zero exposure, which makes it difficult to set ambitious, aggressive goals. This is compounded by the legality of pesticides; they are not "end of the pipe" pollution, but substances legally in the environment. OPP must balance its dual mission of providing a gateway to the marketplace for pesticide products with the protection of the public from harmful pesticide exposures. Further, determining attribution for changes in pesticide residue in humans as a result of EPA actions taken is problematic.

FQPA Logic Model Can Improve Performance Measuring

Logic models and performance indicators are tools to provide better performance measures and, thus, program management decision making. Our prior January 10, 2006 FQPA report (2006-P-00009) addressed how logic models distinguish outputs and outcomes in program design. OPP developed logic models for individual programs during its current performance measurement initiative, but did not develop a logic model for the pesticide program as a whole.

The logic model in Figure 2.2, prepared by the EPA OIG, provides an overarching picture of OPP's FQPA-related activities and potential outcomes. Those measures, activities, and resources in orange boxes are currently used by OPP. Those in green boxes are proposed and/or prospective measures. Some of the measures are proposed by OPP (shown in Appendix B); others come from literature related to pesticide performance measurement. The logic model illustrates the potential flow from activities through long-term outcomes from OPP actions.

Figure 2.2: Logic Model on FQPA Implementation and Children's Pesticide Exposure Health Risk Mitigation



OIG staff developed this logic model based on data collected for this evaluation.

EPA Should Consider Revising Goal Structure

The structure of EPA's Goal 4 is currently not set up to accomplish or measure human health or environmental outcomes. OPP has the potential to measure ambient conditions, body burdens, quantities and toxicities of pesticides sold, and residue levels, but cannot currently tell the public anything about these elements because the current goal structure does not reflect the fact this is part of its mission. OPP said that the existing structure is highly output-oriented, and does not correlate well with OPP's three major mission areas (see Figure 2.3).

OPP has proposed a new goal structure for its portion of Goal 4 that outlines changes for three major mission areas – human health, the environment, and other benefits – as shown in Figure 2.3:

Figure 2.3: Existing and Proposed Goal 4 Structure for EPA Strategic Architecture

Goal 4: Healthy communities and ecosystems	
Existing Structure	**Proposed Structure**
4.1 Chemical, organism, and pesticide risks	**4.2.1** Protect **human health** from pesticide risk
4.1.1 Reduce exposure to toxic pesticides	**4.2.2** Protect the **environment** from pesticide risk
4.1.2 License pesticides meeting safety standards	**4.2.3** Realize the **benefits** from pesticide use

OIG staff developed figure based on data collected during evaluation.

The proposed strategic plan structure is more outcome-oriented, and better addresses OPP's strategic goals. OPP wants the goal structure to acknowledge OPP's dual role as a gateway to the market for pesticide products and as a steward of human health and the environment. The proposed goal structure reflects this dual role. OPP officials have expressed this concern to the Office of the Chief Financial Officer in the past. The 2006-2011 EPA Strategic Architecture drafted by the Office of the Chief Financial Officer incorporated OPP's proposed structure and strategic goals, and allows for the development and use of outcome-based performance measures.

One problem with the existing goal structure is that the reregistration program will be ending in August 2006, turning into the registration review process, as outlined under FQPA. Although the registration and reregistration processes provide support for what OPP does, they are activities, not outcomes. OPP's performance measures and budget will be merged by the end of this process, and the proposed goal structure better allows for the merging of measures, goals, and budgeting.

Recommendations

We recommend that the Director, Office of Pesticide Programs:

2-1 Continue to move away from focusing primarily on outputs when examining the human health and environmental impacts of work by continuing the current measurement initiative.

2-2 Implement the following three human health performance measures in the next round of strategic planning:

- Reduce the number of acute poisoning incidents from pesticides in and around the home.
- Reduce the level of currently registered pesticides in the general population.
- Reduce pesticide residues in the 20 foods most commonly eaten by children using Pesticide Data Program residue data.

2-3 Work with other EPA program offices and other Federal agencies to ascertain supporting data for new measures of FQPA results.

We recommend that the Chief Financial Officer:

2-4 Revise the Goal 4 structure in the next round of strategic planning to create a more outcome-oriented goal structure and to acknowledge OPP's dual role as a gateway to the market for pesticide products and as a steward of human health and the environment.

Agency Response and OIG Evaluation

The Agency agreed with the recommendations provided in Chapter 2, and believes that many of our suggested measures support its current system of measurement. Appendix A provides the full text of the Agency's response.

Chapter 3
Suite of Performance Measures Can Help OPP Better Measure Impact

By integrating data into a suite of performance measures, OPP can better utilize existing data to track the effectiveness of pesticide regulatory decisions and program performance. We identified several pools of quantitative data available for use as performance indicators. To manage FQPA performance indicators effectively, coordination between OPP staff, other EPA offices, and external entities is needed. Developing a suite of performance measures will facilitate such an approach.

Using a Suite of Performance Measures Can Help OPP Track Progress

While OPP has limited in-house data on human health effects, there are numerous databases and data sources external to EPA that can provide information for developing health-based outcome measures. Integrating this data into a suite of performance measure can better enable OPP to measure progress.

For example, biomonitoring data are helpful in tracking trends and extremes of pesticide exposure. Biomonitoring is the term given to the analysis of biological samples (e.g., human blood, bodily tissues and fluids, and breast milk) to identify the presence and levels of specific substances in the body. By comparing levels in one individual to normal levels in the general population, and then comparing them to levels recognized by the medical community to cause harm, scientists and public health officials are able to make more accurate and effective decisions to prevent illness and protect the public. However, biomonitoring data alone do not constitute a complete pesticide exposure risk assessment, since exposure to multiple pesticides from many sources rather than just one pesticide from one source is a routine part of life for children.

Integrated environmental monitoring and health tracking systems that employ well-validated performance indicators can enable EPA officials to scan for potential causes or triggers of changes in trends and patterns. The following is a list of existing data sources from which OPP can pull integrated outcome performance measurement information:

- The *National Report on Human Exposure to Environmental Chemicals,* from National Health and Nutrition Examination Surveys
- Pesticide residual data from the:
    - Pesticide Data Program managed by USDA's Agricultural Marketing Service
    - Total Diet Study, sometimes called the Market Basket Study, by the Center for Food Safety and Applied Nutrition of the Food and Drug Administration within the Department of Health and Human Services
- The Agricultural Health Study
- Research data from the various EPA-funded Centers for Children's Environmental Health and Disease Prevention Research
- Poison Control Centers Data
- Pesticides Industry Sales and Usage Data
- National Home & Garden Pesticide Use Survey

OPP is currently looking for new opportunities to gather data for non-occupational exposures, including what can be targeted in future rounds of the National Health and Nutrition Examination Surveys. OPP plans to target groups of chemicals by class to provide a historical, retrospective picture of OPP impact. In addition, OPP plans to do more collaborative work with the other EPA offices, such as the Office of Water, to ascertain whether there is any additional data in-house that OPP could use in developing FQPA performance indicators.

Although these data sources are available to OPP, we found little evidence to suggest OPP mines datasets to uncover less-obvious human health effects, such as developmental health risks or long-term diseases. Although some data from the list above could be used as stand-alone performance indicators, others should be grouped during analysis to uncover effects from regulatory decisions or complex interactions requiring regulatory interventions. This grouping of measures will provide a "suite" of measures from which OPP can garner trends and impact. Using a suite of FQPA performance measures would demonstrate OPP performance in mitigating children's pesticide exposure risk and enhancing public health from reduced risk pesticide usage.

In Table 3.1, we outline potential FQPA performance measures from existing data sources and how these measures can be used in a suite. In the absence of ideal end outcome measures of human health, the Agency could employ a suite of surrogate measures. For example, dietary consumption data from the National Health and Nutrition Examination Survey can be paired with pesticide residue data analyzed by the USDA's Pesticide Data Program and the Food and Drug Administration's Total Diet Study to determine pesticide exposures from ingestion. Examining these measures along with information on the frequency of foods consumed with nonviolative pesticide residues could confirm effectiveness of OPP's pesticide tolerance determinations.

Table 3.1: Examples of Suites of Measures to Illustrate Children's Pesticide Exposure Levels, Body Burdens, and Possible Health Effects

Data Sources	Possible Measures (Using Existing Data)	Potential Measures (No National Data currently exists)	Indicators of:		
			Protection of children's health	Impact of OPP actions on use	Impact of FQPA on behavior
Pesticide Residual Data from Agricultural Marketing Service, USDA's Pesticide Data Program	• Dietary risk trends from domestic vs. imported foods. • Pesticide exposure risk from drinking water and water treatment processes. • Effects of regulatory decisions in mitigating risk sources. • Risk-drivers from chemical trading or substitutions.	• Meta measures: Food and water consumption data linked to pesticide residue analysis and violations.	√	√	
Dietary: Total Diet Study & Food Market Basket Surveys	• Compliance with tolerances.				
National Health and Nutrition Examination Survey	• Measure of contaminants and body burdens. • Pesticide residue levels in drinking water quality. • Residential dust/ambient exposures. • Dietary consumption information matched with biomarker and pesticide residue information.	Pesticides and their metabolite levels in • Human umbilical cord blood. • Birth outcome (weight and length). • Paraoxonase 1 (PON1) activity. • Human breast milk.	√	√	√
Poison Control Centers Data	• Acute illnesses associated with pesticide exposures at schools and municipal parks.	• Schools and municipal parks participating in Integrated Pest Management programs.		√	√
Farm Family Pesticide Exposure Data: Farm Family Pesticide Exposure Study and Studies in the Agricultural Health Study	• Health effects among farmers' wives at reproductive age. • Birth weights, birth defects, and asthma/chronic respiratory diseases among farmers' children.	• Spray drift and acreage treatment data. • Birth outcome data. • Asthma data.	√	√	√
Pesticides Industry Sales and Usage Data	• Risk-drivers from chemical trading or substitutions. • Economic profile/regulatory impacts on industry.	• Market share of reduced risk pesticides.		√	
National Home & Garden Pesticide Use Survey	• Trends from self-reported home and garden pesticide use data • Trends in residential usage, reduced risk pesticide sales, and acute poisoning data.	• Self reported residential usage data.		√	√

OIG staff developed figure based on data collected during evaluation.

Five Examples Demonstrate Use of Suite Approach

The following five examples show how a suite of performance measures using external sources could help OPP track regulatory progress and demonstrate effectiveness of FQPA-relevant decisions. Each example focuses on observable, quantifiable exposure and offers a long-term strategic picture of the gap between regulatory actions and outcomes of children's health. Collectively, they offer broad measures of the effectiveness of the pesticide programs' aggregate effects on children's health. In addition, some of these examples focus on the type of developmental and exposure data that may be necessary for future pesticide registrations.

Example 1: Research results reported by the Centers for Children's Environmental Health and Disease Prevention Research[3] illustrate the importance of using a suite of measures to highlight regulatory pesticide exposure risk mitigation efforts by EPA. Three recent studies[4] appearing in the journal *Environmental Health Perspectives* examined the relationship between pregnant women's exposures to selected pesticides and birth outcomes. Participants in each study were likely exposed to many classes of pesticides as well as other environmental chemicals, but the focus of these studies was on organophosphorus pesticides.

Example 2: One major advantage of using biomarker data from the National Health and Nutrition Examination Survey is that the data provide an ongoing assessment of the U.S. population's exposure to environmental chemicals using biomonitoring. Centers for Disease Control and Prevention scientists measure chemicals or their metabolites (breakdown products) in blood and urine samples from selected participants in each survey, and the chemical analysis of environmental monitoring samples collected during each survey. Analytical results are published in the *National Reports on Human Exposure to Environmental Chemicals.* Human exposure data from the survey would allow EPA officials to track children's body burden trends and determine whether past and current regulatory actions are effective in reducing or mitigating pesticide exposure risks for children and women of childbearing age.

Example 3: In Chapter 4, we noted the use of an empirical approach to examine and document OPP's performance in mitigating dietary pesticide exposure risks for children from domestic foods that they consume frequently. If OPP carries our analysis one step further, it could track actual consumption risks by

[3] Funded by EPA in partnership with the National Institute of Environmental Health Sciences and the Centers for Disease Control and Prevention.

[4] Berkowitz, Gertrud S et al. In Utero Pesticide Exposure, Maternal Paraoxonase Activity, and Head Circumference. *Environmental Health Perspectives* 112:388-391, 2004. Eskenazi, Brenda et al. Association of in Utero Organophopshate Pesticide Exposure and Fetal Growth and Length of Gestation in an Agricultural Population. *Environmental Health Perspectives* 112:116-1124, 2004. Whyatt, Robin M et al. Prenatal Insecticide Exposures and Birth Weight and length among an Urban Minority Cohort. *Environmental Health Perspectives* 112:1125-1132, 2004.

integrating food and water pesticide residue measures from USDA's Pesticide Data Program with the National Health and Nutrition Evaluation Survey data on children's actual food consumption amounts and urinary biomonitoring.

Example 4: External stakeholders continue to express concern over the health of farm workers and their families from pesticide exposures. Two pools of data are available to EPA for using real-world pesticide exposure information on farmers and their families to track progress in pesticide exposure risk management: the Farm Family Pesticide Exposure Study and the substudies of Agricultural Health Study. Such studies are epidemiological-based and use health outcomes, along with biomonitoring of pesticides in urine, to quantify the exposure of farmers/applicators and their families. Also, the Centers for Children's Environmental Health and Disease Prevention Research conduct research on farm families and their children.

Example 5: EPA collects information about pesticide poisonings by a variety of mechanisms. In 2004, approximately 70,000 children were accidentally exposed to or poisoned by pesticides. OPP has used Poison Control Centers' data to show information on how EPA is improving protection from acute adverse effects of pesticide exposure. OPP receives mandated reports of adverse effects from manufacturers, and periodically reviews both the Toxic Exposure Surveillance System data maintained by the American Association of Poison Control Centers and aggregated data from State-based surveillance programs. A 2005 study was published in the *Journal of the American Medical Association* that illustrated the importance of tracking risks of pesticide use in and around the nation's schools. We believe EPA can further analyze available data from State and toxic exposure surveillance systems to extract pertinent pesticide poisonings trends in schools and childcare centers.

Recommendation

We recommend that the Director, Office of Pesticide Programs:

3-1 Evaluate the use of suites of performance measures to more comprehensively assess OPP's FQPA implementation performance and impacts on children's health.

Agency Response and OIG Evaluation

The Agency agreed in general with the recommendation provided in Chapter 3. OPP noted that measures are only as good as the data upon which they are based, and have concerns that such data do not exist for some of our recommended measures. OPP additionally stated that it will consider the measures provided and further evaluate the recommendation as they make progress in implementing FQPA performance measures. Appendix A provides the full text of the Agency's response.

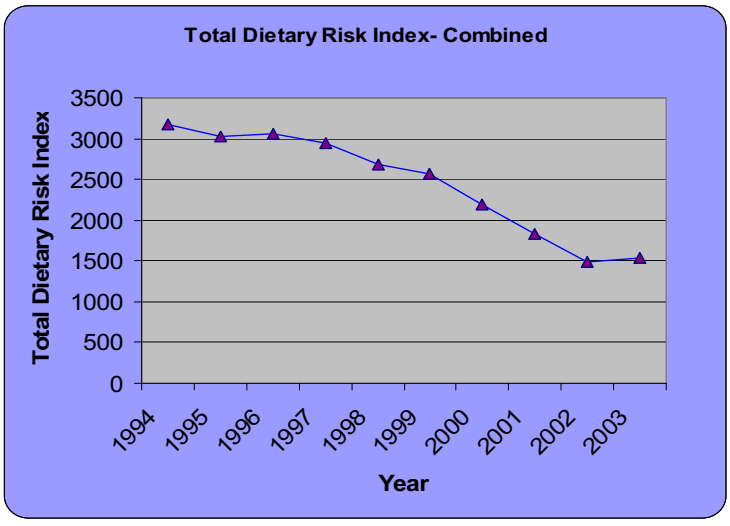
Chapter 4
OPP Decisions on Pesticide Dietary Exposure Risk Had Positive Impact

OPP has not yet stated the impact of its performance under FQPA on children's health. As discussed in Chapter 2, this occurred because OPP did not have adequate measures. To get a general idea on the impact of OPP's actions on children's health based on the FQPA, we examined pesticide dietary risk. Dietary risk is based on both the exposure to a pesticide and the pesticide's toxicity. We conducted an analysis of the dietary pesticide residue data from USDA's Pesticide Data Program and found that EPA's regulatory actions had a significant impact in reducing pesticide exposure risk. Risks associated with 16 foods commonly eaten by children declined almost 50 percent. However, while we noted positive changes for domestic foods, there has been a shift of risk to imported foods.

FQPA Actions Decreased Dietary Pesticide Risks to Children

Using USDA's Pesticide Data Program data, we found that risks associated with 16 foods commonly eaten by children declined by almost 50 percent. Specifically, as illustrated in Figure 4.1, the total dietary risk index amount (domestic and imported combined) decreased from 3,170 in 1994 to 1,532 in 2003.[5]

Figure 4.1: Total Dietary Risk Index Scores for Selected Children's Foods[6]

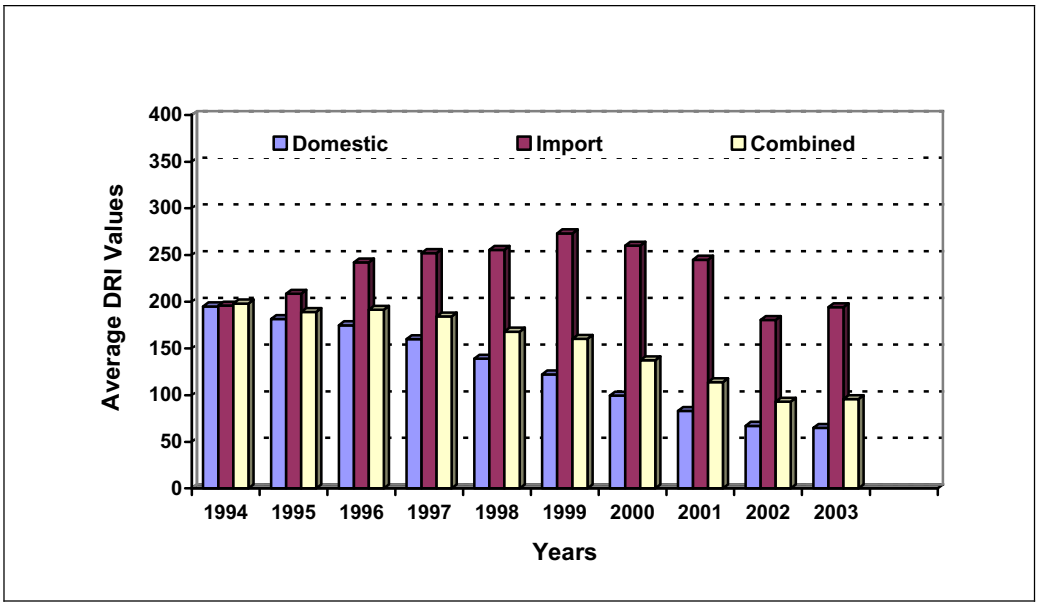


[5] 2003 is currently the last year for which data is available through USDA's Pesticide Data Program.
[6] Certain years included in our sample lacked data. For these years, the trend data and data points are extrapolated. Details on dietary risk index values for selected foods are in the supplemental report.

To evaluate the impact of the FQPA on dietary pesticide exposure risk for children, we analyzed data on food intake and exposure to food pesticide residues. The methodology we developed is discussed in our supplemental report. The Dietary Risk Index is a basic unit of measure the OIG team used to track pesticide dietary risks for food commonly consumed by children. Our index values are based on risk assessment methods and publicly available toxicological data supporting EPA dietary risk assessment.

We found risks have declined by about two-thirds in domestically grown foods in 16 important children's foods[7] included in our analysis. Figure 4.2 illustrates that between 1996 (when FQPA was implemented) and 2003, the average Dietary Risk Index values across the 16 domestically produced foods declined from 175 to 65, or about 63 percent.

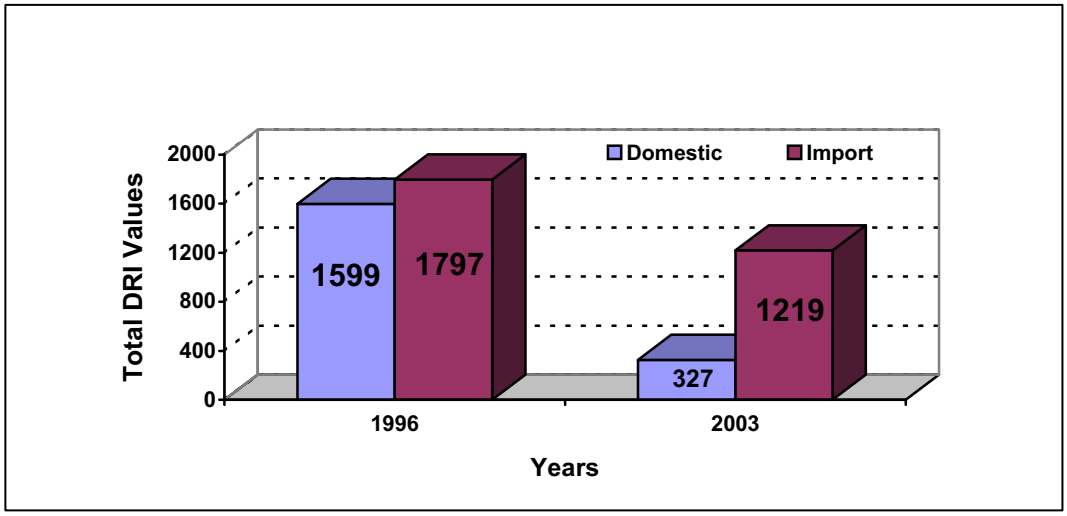
Figure 4.2: Average Total Dietary Risk Index Values for Selected Foods



A similar analysis was conducted on pesticide residues in imported samples. Although there was a decline in the total imported food dietary risk index, the decline was not nearly as significant as it was for domestic foods. On a serving-compared-to-serving basis, dietary risks in 1996 were roughly comparable for imported and domestic foods. By 2003, however, total pesticide residual risk for imported foods were nearly four-times higher than those of the domestic scores (see Figure 4.3).[8] Breakdowns for specific domestic and imported food commodities are in the supplemental report.

[7] Apple juice, apples, broccoli, cantaloupe, carrots, celery, cucumbers, grapes, green beans, lettuce, oranges, peaches, potatoes, spinach, sweet bell peppers, and tomatoes. These foods were selected based on the amount of data points in the Pesticide Data Program database, and the frequency with which they are consumed by children.
[8] The word "total" in our analysis refers to the "total" summed values of the risks we assessed using the Pesticide Data Program data. It is important to note that USDA's sampling is limited. Therefore, "total" does not reflect all foods, but simply the sum of the risk from our analysis and USDA's sampling.

Figure 4.3: Comparisons of Total Pesticide Dietary Exposure Risks in Domestic and Imported Foods



Reduced Risk Attributable to Two Major EPA Actions

FQPA required EPA to evaluate all pesticides specifically to assess their potential damage to the health of infants and children based on complete and reliable data on exposure and the pesticide's toxicity. As part of EPA's ongoing FQPA implementation, EPA began conducting individual assessments of organophosphate pesticides.[9] As a result of this review for two specific organophosphate pesticides, EPA canceled the use of methyl parathion on all fruits and many vegetables and eliminated the manufacturing of chlorpyrifos for nearly all residential uses. According to Agency documents, regulatory actions on individual organophosphate pesticides during the past few years have substantially reduced the risks of these pesticides. Details follow.

Methyl Parathion is one of the most toxic organophosphate pesticides. It can over stimulate the nervous system, causing nausea, dizziness, confusion, and – at high exposures – respiratory paralysis and death. EPA's risk assessment showed that methyl parathion posed an unacceptable risk to infants and children. To mitigate the high dietary risk to children, EPA accepted voluntary cancellation of the use of this pesticide on those crops that contribute most to children's diets. These canceled uses represented 90 percent of the dietary risk to children, dramatically reducing the estimated dietary risk and thus making the risk acceptable for children and all others in the U.S. population.

[9] Organophosphates are a high priority group of chemicals with a common mechanism of toxicity that affects the nervous system, and requires a cumulative risk assessment. They can pose known risks of acute and chronic toxicity to humans and wildlife. They are widely used on many food crops, and in residential and commercial settings.

Chlorpyrifos was one of the most widely-used insecticides in the United States, and was commonly found in many home-and-garden insecticides. Additionally, it was used in some termite treatments and on agricultural crops. In June 2000, EPA released a revised risk assessment and announced an agreement with registrants to phase out and eliminate certain uses of chlorpyrifos. This action eliminated home, lawn, and garden uses by the end of the 2000, as well as all termite-control uses in existing homes and for new home-and-building construction by the end of 2004. Additionally, the use of chlorpyrifos for all sensitive areas, such as schools, day cares, parks, hospitals, nursing homes and malls, were eliminated by the end of the 2000. EPA also canceled the use of chlorpyrifos on tomatoes and restricted the use on apples.

Looking at Pesticide Data Program data, we found a single pesticide like chlorpyrifos accounted for 70 percent or more of total dietary risk contributions in apples grown in the United States between 1999 through 2002. As Figure 4.4 illustrates, risk associated with chlorpyrifos on apples has declined dramatically.

Figure 4.4: Changes on Dietary Exposure Risk from Chlorpyrifos for Apples

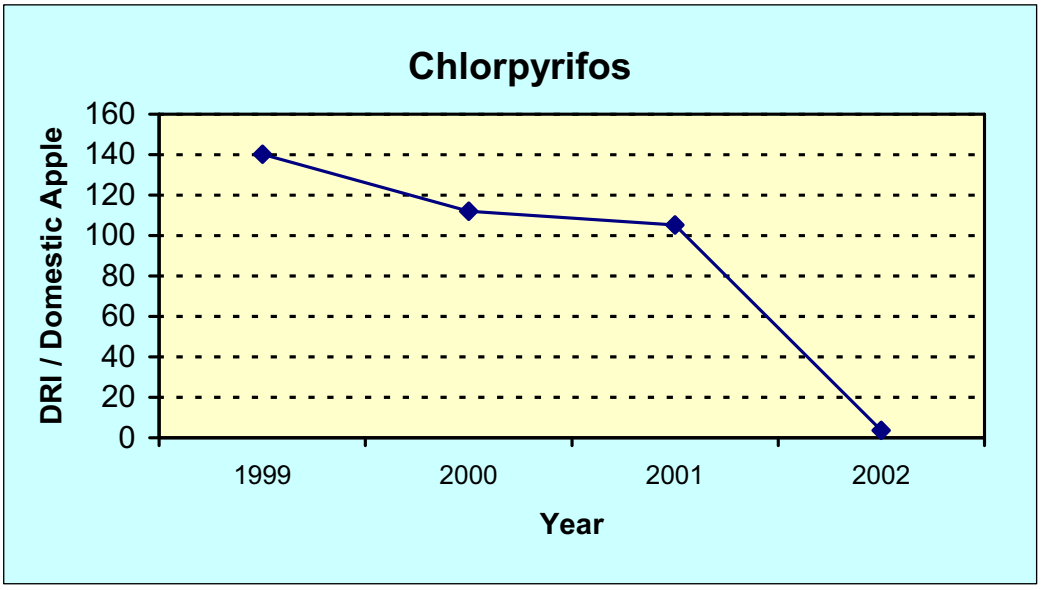


Table 4.1 illustrates that the contribution of chlorpyrifos to total dietary pesticide risk decreased to only 8 percent in domestically grown apples, with the remaining risk coming from newer, lower-risk pesticides.

Table 4.1: Chlorpyrifos as a Single-Risk Driver in Domestically Grown Apples

Year	Total Pesticides Dietary Exposure Risk in Apples	Dietary Exposure Risk Chlorpyrifos/Apple Combination	% of Total
	(Dietary Risk Index Values)		
1999	180.2	140.2	78%
2000	144.3	112.0	78%
2001	144.1	105.2	73%
2002	43.7	3.6	8%

In Table 4.2, we show that EPA's August 1999 regulatory actions against the parathions resulted in a drop of about 83 percent of the total impact in domestic foods triggered. Changes in chlorpyrifos tolerances reduced total Dietary Risk Index values by another 241 points. Taken together, tolerance revocations and reductions imposed on 8 uses of the parathions and chlorpyrifos accounted for 98 percent of the total impact of EPA actions to date on a set of 30 of the most serious domestic "risk drivers." Risk drivers are high risk pesticide-food combinations accounting for the majority of summed pesticide dietary exposure risk. Details are in the supplemental report.

Table 4.2: EPA Regulatory Actions Decrease Dietary Pesticide Exposure Risks

Pesticide	Aggregate Dietary Risk Index/ Year before EPA Action	% Reduction
	(For Domestic Food Samples)	
Parathions	1,369	83%
Chlorpyrifos	241	15%
Total	1,610	98%

Method Could Help OPP

The Dietary Risk Index described in this chapter is one method for OPP to consider in assessing the impact of its performance. This index could be used in combination with the proposed measures and suites of measures recommended in Chapters 2 and 3. We recognize that there are limitations, including cost and data collection constraints, to OPP's use of this methodology. Nonetheless, we believe it is important for OPP to take action to improve its ability to document impacts of the FQPA on dietary risk levels for foods that contribute significantly to the diets of infants and children.

Recommendation

We recommend that the Director, Office of Pesticide Programs:

4-1 Develop a cost-effective and scientifically defensible method to assess its performance in decreasing dietary pesticide exposure risks to children from its tolerance assessments and reassessments.

Agency Response and OIG Evaluation

The Agency agreed in general with the recommendation provided in Chapter 4. OPP noted that under the Federal Food, Drug, and Cosmetic Act, it has regulatory authority to reduce a tolerance only if dietary exposure risks do not meet the "reasonable certainty of no harm" standard established by FQPA. However, OPP also stated that an exposure-based measure utilizing USDA's Pesticide Data Program data offers the best alternative at this time, and that it is always interested in exploring ways to measure the human health and environmental impacts of our work based upon risk-based measurements.

Appendix A provides the full text of the Agency's response.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)[2]	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date[3]	Claimed Amount	Agreed To Amount
2-1	11	Continue to move away from focusing primarily on outputs when examining the human health and environmental impacts of work by continuing the current measurement initiative	O	Director, Office of Pesticide Programs	TBD		
2-2	11	Implement the following three human health performance measures in the next round of strategic planning: • Reduce the number of acute poisoning incidents from pesticides in and around the home • Reduce the level of currently registered pesticides in the general population • Reduce pesticide residues in the 20 foods most commonly eaten by children using Pesticide Data Program residue data	O	Director, Office of Pesticide Programs	TBD		
2-3	11	Work with other EPA program offices and other Federal agencies to ascertain supporting data for new measures of FQPA results	O	Director, Office of Pesticide Programs	TBD		
2-4	11	Revise the Goal 4 structure in the next round of strategic planning to create a more outcome-oriented goal structure and to acknowledge OPP's dual role as a gateway to the market for pesticide products and as a steward of human health and the environment	O	The Chief Financial Officer	TBD		
3-1	16	Evaluate the use of suites of performance measures to more comprehensively assess OPP's FQPA implementation performance and impacts on children's health	O	Director, Office of Pesticide Programs	TBD		
4-1	22	Develop a cost-effective and scientifically defensible method to assess its performance in decreasing dietary pesticide exposure risks to children from its tolerance assessments and reassessments	O	Director, Office of Pesticide Programs	TBD		

[1] O = recommendation is open with agreed-to corrective actions pending;
C = recommendation is closed with all agreed-to actions completed;
U = recommendation is undecided with resolution efforts in progress

[2] Identification of potential monetary benefits was not an objective of this evaluation.

[3] In accordance with EPA Manual 2750, the Agency is required to provide a written response to this report within 90 calendar days that will include a corrective actions plan for agreed upon actions, including milestone dates.

Appendix A

Agency Response

MEMORANDUM

SUBJECT: OPP's Comments on the OIG's Draft Evaluation Report "Measuring the Impact of the Food Quality Protection Act: Challenges and Opportunities" (Assignment No. 2005-001034)

FROM: Jim Jones, Director
Office of Pesticide Programs

TO: Jeffrey K. Harris, Director for Program Evaluation, Cross Media
Office of Inspector General

This memorandum is in response to the recommendations made by the Agency's Office of Inspector General (OIG) in its April 13, 2006, report evaluating EPA's implementation of the Food Quality Protection Act (FQPA). The report, the final in a series of three planned reports, comments on OPP's ongoing work to develop better performance accountability measures.

The EPA's OIG report, "Measuring the Impact of the Food Quality Protection Act: Challenges and Opportunities," focuses upon the following issues:

- What are the strengths and weaknesses of OPP's current measurement system in tracking FQPA objectives, and how could it be improved, if necessary?

- What impact did FQPA have on mitigating dietary pesticide exposure risk and on children's health?

Our response is organized as follows: The first section summarizes our responses to the OIG's specific recommendations. The second section contains more detailed comments on the text of the report.

1. **OPP's Responses to the OIG's Recommendations**

OIG Recommendations

Chapter 2 - "Improvements Needed in OPP's Measurement System."

OIG Recommendation 2-1: Continue to move away from focusing primarily on outputs when examining the human health and environmental impacts of work by continuing the current measurement initiative.

OPP Response: OPP agrees with this recommendation. OPP agrees that our performance measures in the past have primarily been output measures. Although we recognize that there will always be a need to track such outputs, we are striving to develop more direct and effective ways to assess the human health and environmental impacts of our decisions.

OPP recently conducted a multi-year effort with extensive stakeholder input to develop a comprehensive suite of outcome performance accountability measures. The final product of this effort will be the establishment of a comprehensive and consistent set of realistic, meaningful, and supportable outcome performance measures, and steps to ingrain those measures in the program's activities. OPP is working to include these new measures in EPA's strategic plan, and to begin implementation of measures and collection of baseline data.

OIG Recommendation 2-2: Implement the following three human health performance measures in the next round of strategic planning:

- reduce the number of acute poisoning incidents from pesticides in and around the home;
- reduce the level of currently registered pesticides in the general population; and
- reduce pesticide residues in the 20 foods most commonly eaten by children using Pesticide Data Program residue data.

OPP Response: OPP agrees with this recommendation.

The recommended measures comport with the measures OPP is recommending for the Agency's draft strategic plan. However, with regard to the first measure (to reduce incidents in and around the home) OPP's interest is in reducing all incidents – both human and environmental – from all pesticide uses, not just those in and around homes.

OIG Recommendation 2-3: Work with other EPA program offices and other Federal Agencies to ascertain supporting data for new measures of FQPA results.

OPP Response: OPP agrees with this recommendation. For many years, OPP has worked extensively with other program offices within EPA, as well as other Federal (e.g., USDA, DHHS/CDC) and state agencies, to use the results of their studies and data collection as indicators in measuring results of FQPA implementation. EPA plans to continue such collaboration.

OIG Recommendation 2-4:
We recommend that the Director, Office of the Chief Financial Officer:
Revise the Goal 4 structure in the next round of strategic planning to create a more outcome-oriented goal structure and to acknowledge OPP's dual role as a gateway to the market for pesticide products and as a steward of human health and the environment.

OPP Response: OPP is in discussion with the Office of the Chief Financial Officer regarding our dual role as gateway to the market and steward of human health and the environment as it relates to Goal 4.

Chapter 3 - "Suite of Performance Measures Can Help OPP Better Measure Impact."

OIG Recommendation 3-1: Evaluate the use of suites of performance measures to more comprehensively assess OPP's FQPA implementation performance and impacts on children's health.

OPP Response: OPP appreciates OIG's suggestions for developing a proposed suite of measures. The list of potential performance measures and examples given in Table 3.1 presents thoughtful examples of approaches using different data sources to measure the impacts of FQPA implementation. OPP has had a history of using information from listed and other data sources to make more informed science and regulatory decisions. OPP has also given significant consideration to using these data sources to formulate meaningful measures but has recognized that data sources often have limitations (e.g., quality, quantity or focus of data) which may affect our use of those data for valid and desirable measurements. OPP provides further discussion on this issue below under Technical Comments.

OPP generally supports the concept of using a suite of measures to evaluate impacts. However, measures are only as good as the data upon which they are based. In general, the data need to be: 1) of high quality, statistically representative of the population and directly related to the measure; 2) collected over a time frame sufficient to show trends; and 3) collected in a consistent manner to permit meaningful comparisons across different collection intervals. For the most part, such data sources are very limited. The exceptions appear to be PDP and FDA compliance data; Poison Control Center (PCC) data; NHANES data; and possibly pesticide sales and usage data.

A group of similar data can be pooled to provide a "snap-shot" of the impact of OPP's actions upon public health. While a snap-shot of data cannot be used to provide information on trends, it can be used for identifying potential new measures.

Again, OPP appreciates OIG's thoughtful development of a proposed suite of measures, and will consider them and further evaluate the recommendation as we make progress in implementing FQPA performance measures. We welcome new ideas and studies for finding appropriate measures of our performance.

Chapter 4 – OPP Decisions on Pesticide Dietary Exposure Risk Had Positive Impact

OIG Recommendation 4-1: Develop a cost-effective and scientifically defensible method to assess its performance in decreasing dietary pesticide exposure risks to children from its tolerance assessments and reassessments.

OPP Response: OPP generally agrees with this recommendation. It should be noted that under FFDCA, OPP has regulatory authority to reduce a tolerance only if dietary exposure risks do not meet the "reasonable certainty of no harm" standard established by FQPA.

OPP believes that an exposure-based measure utilizing USDA's PDP data offers a good data source for dietary exposures. In addition, OPP is always interested in exploring ways to measure the human health and environmental impacts of our risk based upon risk-based decisions.

1. **Technical comments**

Page 7: "Although EPA has volumes of data on individual pesticides, OPP is often prohibited from using it due to confidential business information conflicts."
OPP believes this sentence requires correction. The real issue is not that we are "prohibited" from using confidential business information, but that we are prohibited from *releasing* CBI without the owner's permission due to statutory restrictions on the disclosure of CBI. In addition, OPP may release reports with the CBI information redacted. In any case, the CBI material is used in decision making, but ordinarily cannot be made publicly available due to statutory restrictions on the disclosure of CBI. Further, this sentence is misleading because it ignores the fact that safety data on registered or previously registered pesticides are explicitly excluded from CBI protection. 21 USC 136h(d)(1).

Page 9, Figure 2.2:
OPP appreciates OIG's work and thoughtfulness in developing the "Logic Model on FQPA Implementation and Children's Pesticide Exposure Health Risk Mitigation" Figure 2.2. OPP does have an exposure measure for the foods most commonly consumed by infants and children that we have been working to refine. However, OPP agrees that logic modeling can be a useful tool in measures development, and we like the concept of a broader children's health measure. Generally, OPP will consider the OIG's children's exposure/risk logic model as we continue to refine measures of human health and environmental impacts of our work.

OPP has a few additional comments on the suggested logic model. Specifically, the OIG could have included many other critical resources, such as other Federal agencies (USDA for PDP, FDA for tolerance monitoring, CDC for NHANES), state lead agencies who have been supportive of our measurement effort, industry, public interest groups, and other offices within EPA, such as the Office of Water. Another key resource, especially in the area of reducing exposure to pesticides, and mitigation of exposure risks, is OPP's outreach and communication activities to educate the public. OPP's outreach and communication efforts should be included under the heading of "activities."

Page 12:
The leading sentence of the second paragraph states "While OPP has limited in-house data on the health effects of pesticides…" implies our data base on human health effects from pesticides is moderate to inadequate and therefore understates the scope and breadth of information OPP actually has and uses to characterize potential human health effects from pesticides. This also discounts OPP's use of published studies. OPP recommends omitting the word "limited."

Page 12/13:
OPP agrees that several of the studies referenced in this section contain data useful for measuring the impacts of EPA's pesticide regulatory program. For example, OPP intends to develop measures based on the NHANES and PDP data. Data from other sources, while informative, cannot be used to form the basis of a measure for tracking OPP's impact because they do not collect data over different time periods that may be statistically analyzed to show changes and trends (e.g., National Home and Garden Use Study.)

Page 14, Table 3.1:
For the data source "Family Farm Pesticide Exposure Data…" In order to have an indicator of the "Impact of FQPA on Behavior" there should be a commensurate "Impact of OPP Actions on Use." Therefore, all three boxes should be checked in this row.

Page 15, Example 1:
Note: The three studies cited are of interest for identifying a snap-shot of success or a potential problem area. However, because they are one-time studies, they are not useful as a measure of long-term success**.** In addition, it is important to note that these studies do not provide data demonstrating causation or information about trends, which are particularly important for tracking progress that may be used as a meaningful measurement.

Page 15, Example 2:
OPP is currently developing an NHANES measure and we are amenable to examining whether or not the National Report on Human Exposure to Environmental Chemicals may be useful for such a measure.

Page 15, Example 3:
OPP has a measure using PDP data and is developing a measure using CDC's NHANES data. OPP is interested in developing a more accurate and reliable measure using these data. We are also interested in moving from exposure measures to risk-based measurement. To date, all risk measures considered would require direct comparisons of different health effects.

Page 15, Example 4:
OPP supports the creation of a farm health measure and we are aware of the studies referenced in this example. However, we are unaware of data sources that are regularly collected and statistically robust to provide accurate and meaningful measures.

Page 15, Example 5:
As data that are regularly collected, PCC data can provide a basis for a long-term measure. However, the PCC data has some significant limitations; most notably the number of incidents

appears to fluctuate with funding levels of PCC's across the country. If there is less funding, there will be fewer poison control centers, with shorter hours and less data compilation. On a limited basis, other data can be used to augment these data.

Chapter 4, pages 17-22:
OPP believes that it has positively affected the health of children through its implementation of FQPA. We agree that the two specific decisions mentioned were among many that contributed to the improvement of children's health. We are also eager to develop and use a measure that could show how our regulatory programs are affecting public health. Despite considerable effort, OPP has been unable to develop a scientifically sound measure that uses available data and can be implemented efficiently. At present, the most scientifically defensible approach for assessing changes in risk appears to be repetition of the kinds of dietary risk assessments for pesticides that OPP has conducted during the tolerance reassessment program. The repeat risk assessments would need to use updated PDP or FDA residue data that were collected after EPA had taken regulatory actions affecting pesticide use. At present, such an effort appears impractical given OPP's resource levels and its statutory mandates.

OPP is in agreement that a scientifically sound, risk-based measure would provide a more accurate and effective indicator than an exposure measure, and is conceptually preferable. Once a draft measure is developed, it should undergo external scientific peer review and public comment.

OPP questions the validity of the OIG risk measure used to draw the conclusions in this chapter and the Supplemental Report. One of OPP's fundamental concerns with the "risk index" developed by OIG is that it makes no distinction among the potential adverse effects prevented by OPP's actions. For example, this approach could actually give a higher weight to a quickly reversible skin irritation than to a severe birth defect. OPP believes there would be value to a more in-depth review of the index and plans to schedule a meeting for our scientists to talk with the creators of the proposed index.

Page 21:
The sentence: "We recognize that there are limitations to OPP's use of this methodology" should be clarified to explain the limitations.

Supplemental Report: Details on Dietary Risk Data:
OPP appreciates OIG's time and effort in developing the proposed measures in the supplemental report. We will consider these suggestions as we continue with development of meaningful measures.

Appendix B

OPP's Proposed Goal-Related Measures

ID #	Measure	Goal
Human Health		
HH1	Reduce the concentration of specific pesticides detected in the general population by 50% by 2011	Provide aggregate picture of effectiveness of OPP actions on U.S. population
HH2	Measure concentration in drinking water and raw water over time as a result of mitigation	Show impact of regulations and mitigation on pesticides in drinking water over time
HH3	Reduce pesticide residues in 20 foods most commonly eaten by children using Pesticide Data Program residue data	Show how combined efforts within OPP have reduced pesticide exposure to children
HH4	Ensure efficacious public health antimicrobial products in the marketplace	Assure that antimicrobial products registered and on market efficacious
HH5	Reduce number of acute poisoning incidents from pesticides in and around the home	Capture reductions in number of adverse effects associated with residential exposure
Worker Safety		
WS1	Survey of agricultural workers' awareness of Worker Protection Standard provisions	Increase awareness of agricultural worker protection provisions for agricultural employees
WS2	Increase in percent-change in Worker Protection Standard planned use compliance ratio over time (# establishments in compliance with Worker Protection Standard/ # inspections)	Have all employers in compliance with Worker Protection Standard
WS3	Percent-change in number of Worker Protection Standard violations for each category over time (# Worker Protection Standard violations/# inspections)	Have agricultural employers and employees use knowledge and skills to reduce pesticide risk in workplace
WS4	Protect those occupationally exposed to pesticides by improving or sustaining the extremely low rate of 3.5 or less incidents per 100,000 potential risk events.	Improve health of occupational pesticide workers
WS5	Reduce number of certified applicators with repeated enforcement violations	Change behavior of certified applicators out of compliance with pesticide laws and label directions
WS6	Improve the health of those who work in or around pesticides by reaching a 50% targeted reduction in moderate to severe incidents for six acutely toxic agricultural pesticides with the highest incident rate.	Improve health of occupational pesticide workers

Appendix C

Distribution

Office of the Administrator
Assistant Administrator for Prevention, Pesticides, and Toxic Substances
Assistant Administrator for Research and Development
Chief Financial Officer
Director, Office of Pesticide Programs
Acting Director, Office of Children's Health Protection
Associate Director, Field and External Affairs, Office of Pesticide Programs
Agency Followup Official (the CFO)
Agency Followup Coordinator
Audit Followup Coordinator, Office of Prevention, Pesticides, and Toxic Substances
Audit Followup Coordinator, Office of Research and Development
Audit Liaison, Office of Pesticide Programs
General Counsel
Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for Public Affairs
Acting Inspector General