OFFICE OF INSPECTOR GENERAL

*Catalyst for Improving the Environment*

## Evaluation Report

# Changes Needed to Improve Public Confidence in EPA's Implementation of the Food Quality Protection Act

**Report No. 2006-P-00003**

**October 19, 2005**

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**Abbreviations**

| | |
|---|---|
| APA | Administrative Procedure Act |
| DEEM | Dietary Exposure Estimation Model |
| EPA | Environmental Protection Agency |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FQPA | Food Quality Protection Act |
| GAO | Government Accountability Office |
| NRDC | Natural Resources Defense Council |
| OIG | Office of Inspector General |
| OPP | Office of Pesticide Programs |
| ORD | Office of Research and Development |

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

U.S. Environmental Protection Agency
Office of Inspector General

2006-P-00003
October 19, 2005

# At a Glance

*Catalyst for Improving the Environment*

## Why We Did This Review

We initiated this review to evaluate the Environmental Protection Agency's (EPA's) activities to implement the Food Quality Protection Act (FQPA) of 1996. We sought to determine whether EPA allows for sufficient public participation in the pesticide decision-making process.

## Background

FQPA changed the way EPA regulates pesticides. FQPA emphasized the potential for infants and children to be especially sensitive to pesticides and the need to provide them adequate protection. FQPA imposed many new requirements on EPA, including the need to review and reregister older pesticides to ensure they meet newer standards.

**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/2006/20051019-2006-P-00003.pdf**

**To view attachments to EPA's response, click on:**
**www.epa.gov/oig/reports/2006/20051019-2006-P-00003A.pdf**

# *Changes Needed to Improve Public Confidence in EPA's Implementation of the Food Quality Protection Act*

## What We Found

This is the first in a series of planned reports on the Agency's FQPA implementation efforts. To ensure adequate protection of children, FQPA required EPA to make significant changes to the pesticide reregistration process. Despite numerous changes to the process, internal and external stakeholders expressed continued reservations over aspects of the process.

EPA allowed public comment periods when developing the Agency's major FQPA science policy papers, and developed and implemented a public comment policy for all pesticide reregistrations in 2002. Prior to this policy, however, the Office of Pesticide Programs did not always solicit public comments prior to issuance of final pesticide reregistration decisions. We believe EPA must ensure that at least one public comment period is held prior to final pesticide reregistration decisions. Providing opportunities for public participation is important for increasing transparency, improving decision making, and increasing overall public confidence.

Though EPA has an on-going research agenda related to the protection of subgroups, OPP lacks a methodology to identify and assess major subgroups of consumers, such as farm children, in the pesticide reregistration decision making process. EPA should respond promptly and directly to requests and petitions from external stakeholders. Such a methodology and responsiveness are needed to improve public confidence.

## What We Recommend

We recommend that EPA's Office of Pesticide Programs allow at least one formal public comment period prior to the issuance of final and interim reregistration decisions. We recommend that the Office develop a defined methodology for considering subgroups, and work with the Office of Research and Development to continue to address these issues. We also recommend that EPA respond promptly to requests and petitions from external stakeholders. EPA generally agreed with the recommendations, although the Agency expressed concern that our report did not sufficiently discuss their efforts. We made revisions when appropriate.

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

OFFICE OF
INSPECTOR GENERAL

October 19, 2005

**MEMORANDUM**

SUBJECT: Changes Needed to Improve Public Confidence in EPA's Implementation of the Food Quality Protection Act
Report No. 2006-P-00003

FROM: Jeffrey K. Harris /s/
Director for Program Evaluation, Cross Media Issues

TO: Jim Jones
Director, Office of Pesticide Programs

This is a final report on the subject review 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 identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and the findings contained in this report do not necessarily represent the final EPA position. Final determinations on matters in the report will be made by EPA managers in accordance with established resolution procedures.

**Action Required**

In accordance with EPA Manual 2750, you are required to provide a written response to this report within 90 days of the date of this report. 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. For your convenience, this report will be available at http://www.epa.gov/oig/.

If you or your staff have any questions, please contact me at (202) 566-0831 or Jerri Dorsey, Project Manager, at (919) 541-3601.

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# Chapter 1
# Introduction

## Purpose

We initiated this review to evaluate the 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. This report is the first in a series of planned reports to inform EPA leadership and interested stakeholders on the Agency's FQPA implementation efforts.

EPA's Office of Pesticide Programs (OPP) seeks stakeholder consultation and public involvement as a critical step in making the Federal pesticide program work. According to OPP, one of the five key FQPA implementation principles is openness. Specifically, Agency documents state that public access to information and consultation with stakeholders will be an integral part of the policy and program development in implementing the requirements of FQPA. To address perception issues regarding OPP's lack of transparency in implementing FQPA, we specifically sought to determine:

- How consistently OPP allows for public comment and participation in the pesticide decision-making process?

- What guidance OPP has in place to address major identifiable subgroups of consumers and to respond to petitions and requests received from external stakeholders?

## Scope and Methodology

We 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 2004 to May 2005.

During our review, we spoke with officials from EPA's OPP, Office of Children's Health Protection, and Office of Research and Development. We also consulted the U.S. Department of Agriculture, Office of Management and Budget, and Department of Health and Human Services. Further, we contacted the following external stakeholder groups, which included industry, environmental organizations, and children's health advocates:

- Children's Environmental Health Network
- CropLife America
- Farmworker Justice Fund
- Natural Resources Defense Council
- Environmental health scientists, toxicologists, and epidemiologists
- Pediatricians/physicians
- Environmental law professors from universities
- Children's Environmental Health Research Centers
- Pest Management Regulatory Agency (Canada)

During our evaluation, we conducted a literature review and reviewed documents pertinent to EPA's implementation of FQPA. We reviewed the legislative history in order to evaluate the intent of FQPA. We also reviewed case decisions and the requirements on the Agency's response to formal petitions from external stakeholders. There were no pertinent reports on which to follow up during this review.

To determine to what extent OPP allowed public comment and participation in the pesticide decision-making process since the passage of FQPA, we reviewed a sample of final and interim reregistration eligibility decisions from FQPA's passage in 1996 through the present (October 1, 1996 through February 28, 2005). The universe of 84 included both final and interim reregistration eligibility decisions. We performed a qualitative analysis of a random sample of 29 decisions. This sample represented 35 percent of all post FQPA reregistration decisions. The sample was selected assuming a 95-percent confidence level and a 15-percent margin of error for the entire universe of decisions over this period of time.

## Results of Review

FQPA required EPA to make significant changes to the reregistration process, including the introduction of aggregate exposure assessment, cumulative risk assessment, and an expedited tolerance reassessment process. Despite numerous changes to the pesticide registration process, both internal and external stakeholders expressed continued reservations over aspects of the process.

We found that EPA allowed public comment periods when developing the Agency's major FQPA science policy papers, and developed a public comment policy for all pesticide registrations in 2002. However, prior to this policy and during the reregistration of a number of highly toxic pesticides, OPP did not always solicit public comments prior to issuance of final pesticide reregistration decisions. We believe EPA must ensure that at least one public comment period is held prior to final pesticide reregistration decisions. Providing opportunities for public participation is important for increasing transparency, improving decision making, and increasing overall public confidence.

Additionally, we determined that EPA lacks guidance on involving the public in selected FQPA-related processes. To address certain shortcomings, EPA needs to provide guidance on identifying and assessing major subgroups of consumers, such as farm children, and should respond promptly to requests and petitions from external stakeholders. Such guidance and responsiveness are needed to improve public confidence.

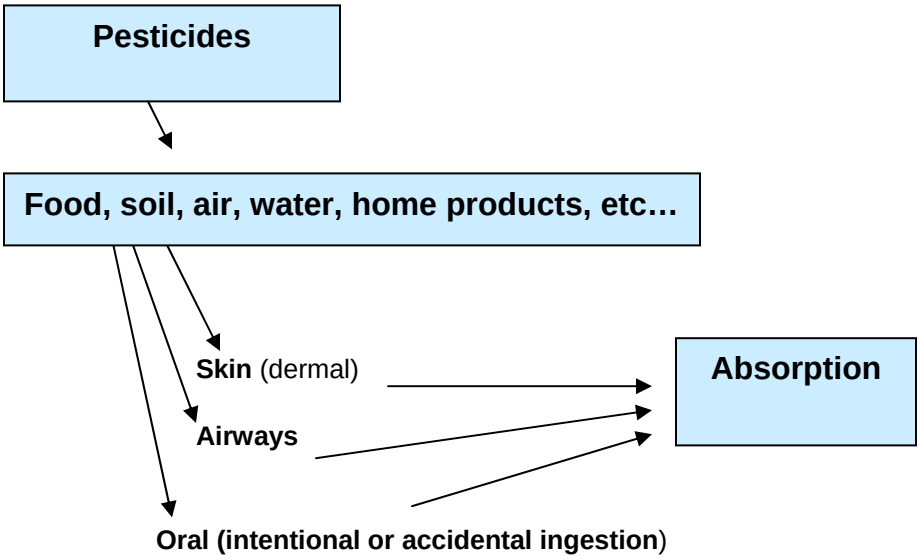
The Agency concurred with many of the recommendations. However, the Agency expressed concerns in the way OPP's performance was characterized in the report. We summarized the comments and provided our evaluations at the end of each chapter with recommendations. The full text of EPA's memorandum and comments is in Appendix A, while additional attachments to that memorandum are available at http://www.epa.gov/oig/reports/2006/20051019-2006-P-00003A.pdf. Additionally, the full text of our comments on EPA's response is available in Appendix B.

# Chapter 2
# EPA and the Food Quality Protection Act

## Pesticides in the United States

EPA defines a pesticide as any substance intended to destroy, prevent, or repel pests, such as insects, weeds, fungi, and rodents. Pesticides are an integral part of agriculture. Many household products are pesticides, including: cockroach sprays and baits; insect repellents for personal use; flea and tick sprays, powders, and pet collars; kitchen, laundry, and bath disinfectants and sanitizers; products that kill mold and mildew; and even some swimming pool chemicals. Once released into the environment, pesticides have the potential to pollute rivers, groundwater, air, soil, wildlife, and food. Human exposure to pesticides can occur through multiple pathways, including from breathing, drinking, and eating, and through skin absorption (see Figure 2.1). Reported health effects from chronic pesticide exposures include cancer, cognitive dysfunctions, altered immune responses, endocrine disruptions, and deterioration of the nervous system and body organs.

**Figure 2.1: Pathways of Exposure**




***Source:*** **EPA Office of Inspector General.**

Children are uniquely susceptible to the health threats posed by pesticides, in both household chemicals and in 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. This includes hand-to-mouth behavior and time spent close to the floor.

## Food Quality Protection Act

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. The National Academy of Sciences recommended an explicit determination that pesticide tolerances were safe for children.

According to EPA, FQPA provided a more consistent pesticide regulatory scheme by amending the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Under FIFRA, EPA registers pesticides for use in the United States and prescribes labeling and other regulatory requirements. Under FFDCA, EPA establishes tolerances for pesticide residues in food, both domestically produced and imported. A tolerance is the maximum level of pesticides residue allowed in or on human food and animal feed. The following outlines many of the FQPA requirements and amendments to FIFRA and FFDCA as interpreted by EPA:

**FQPA Impact on EPA's Regulatory Process**

- Requires EPA to incorporate a 10-fold safety factor to further protect infants and children unless reliable information in the database indicates that it can be reduced or removed.
- Requires EPA to consider cumulative effects from aggregate exposure to compounds with common mechanism of toxicity.
- Establishes a single safety standard under FFDCA by which EPA is to set tolerances--not a risk/benefit standard (with some exceptions).
- Requires assessment to include aggregate exposures, including all dietary exposures, drinking water, and non-occupational (e.g., residential) exposures.
- Requires consideration of cumulative effects and common mode of toxicity among related pesticides, and the potential for endocrine disruption effects.
- Requires a special finding for the protection of infants and children.
- Establishes a tolerance reassessment program and laid out a schedule whereby EPA must reevaluate all tolerances that were in place as of August 1996 within 10 years.
- Requires the consideration of infants, children, and other major identifiable subgroups of consumers.

**FQPA Amended FIFRA**

- Requires EPA to periodically review pesticide registrations to ensure that all pesticides meet updated safety standards.
- Reauthorizes registration and deregistration (licensing) of pesticides.

**FQPA Amended FFDCA**

- Repeals the Delaney "zero tolerance" clause for pesticides; replaced with reasonable certainty that no harm to humans come from aggregate exposure.
- Requires EPA to re-evaluate existing tolerances.
- Requires special provisions for infants and children.

FQPA changed the way EPA regulates pesticides. FQPA emphasized the potential for infants and children to be especially sensitive to pesticides and the need to afford them adequate protection. Also, FQPA imposed many new requirements on EPA's registration process for pesticides.

## OPP Made Substantial Changes as a Result of FQPA

A pesticide cannot be legally used if it has not been registered with EPA's OPP. Through the pesticide registration process, EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. EPA evaluates the pesticide's potential impact on humans, animals not being targeted by the pesticide, and the environment.

According to Agency FQPA implementation documents, the new safety standard is driving changes in risk assessment methods and science policies that support regulatory decisions. FQPA required EPA to address a number of new scientific areas related to pesticide regulation. Key to implementing FQPA's science provision was the effort OPP made in developing science policy papers. OPP developed science policy papers in several areas, including:

- 10-Fold Safety Factor;
- Dietary Exposure and Risk Assessment;
- Drinking Water Exposure;
- Residential Exposure;
- Aggregate Exposure and Risk Assessment; and
- Cumulative Risk Assessment for Pesticides with a Common Mechanism of Toxicity.

EPA is reviewing older pesticides (those initially registered prior to November 1984) to ensure they meet current scientific and regulatory standards. This process, called reregistration, considers the human health and ecological effects of pesticides. Upon completion of the review and risk management decision for the pesticide, EPA issues the final reregistration eligibility decision. The final decision summarizes the risk assessment conclusions and outlines any risk reduction measures needed.

FQPA required EPA to reassess all food use tolerances (pesticide residue limits in food) in effect as of August 1996 when the law was passed. EPA must ensure that the tolerances are at safe levels – that there is a reasonable certainty no harm will result from exposure. Over 9,700 tolerance reassessments must be completed within 10 years of FQPA enactment. OPP has integrated reregistration and tolerance reassessment to most effectively accomplish the goals of both programs. A Government Accountability Office (GAO) review noted EPA has made

progress in reassessing tolerances for pesticide residues.[1] GAO reported that as of April 2000, EPA had conducted 3,471 tolerance reassessments (36 percent). According to EPA, the Agency is on schedule to complete tolerance risk assessments by August 2006.

In determining allowable levels of pesticide residues in food, EPA must conduct a comprehensive assessment of each pesticide's risks, considering:

- Aggregate exposure of the public to pesticide residues from all sources, including food, drinking water, and residential uses;
- Cumulative effects of pesticides and other substances with common mechanisms of toxicity; and
- Special sensitivity of infants and children to pesticides.

To accomplish this, the Agency had to develop new aggregate and cumulative exposure and risk assessment methods. OPP developed a framework for conducting cumulative risk assessments on pesticides. However, to date, OPP has not completed any pesticide cumulative risk assessments as required by FQPA. OPP issues an interim decision when a pesticide has undergone the reregistration process but still requires a cumulative risk assessment. According to OPP, final reregistration eligibility decisions will be issued after the Agency completes the cumulative risk assessment.

Details on the reregistration process are in Figure 2.2.

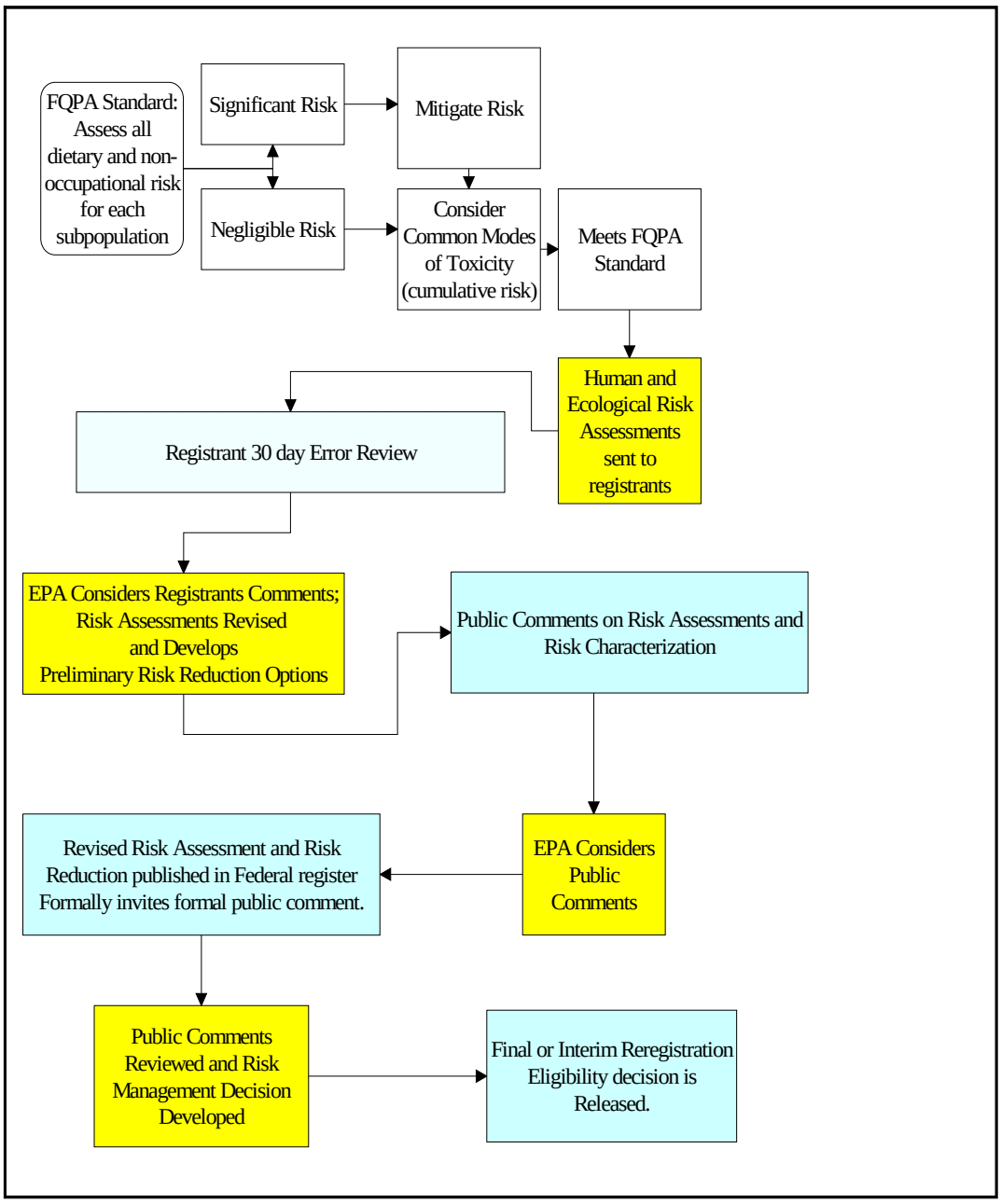
## Stakeholder Concerns

Despite the Agency's efforts to implement the requirements of the FQPA, stakeholders still have concerns with certain internal processes. Those concerns most commonly voiced include: lack of transparency, insufficient data for decision-making, inconsistent application of FQPA requirements, concerns over the lack of protection afforded to subgroups, and lack of outcome measures on FQPA effectiveness.

A number of stakeholders commented on the perception that OPP makes decisions "behind closed doors," thus reducing the transparency of OPP's decisions. Stakeholders raised concerns that OPP frequently consults with industry without providing equal opportunities for consultation with the public and other concerned parties. Some stakeholders expressed concerns over the lack of publicly available information on pesticides and OPP's moving of information off their Web site that once served as a tracking tool for the public.

[1] GAO Report; GAO/HEHS-00-175: "Children and Pesticides: New Approach to Considering Risk is Partly in Place," September 2000.

**Figure 2.2: Decision and Comment Process for Reregistration**




Both environmental and health advocacy organizations stressed their concern over the lack of consideration of subgroups under the FQPA. Subgroups can be examined in terms of variations in dietary exposure, such as for a number of minority communities, or variations in non-dietary exposures, such as for children living in rural agricultural communities and children exposed to pesticides in public housing. Stakeholders feel that EPA has not made a consistent effort to identify and protect potentially susceptible subgroups under the requirements of FQPA.

A number of stakeholders noted that they do not believe the application of or EPA's policies on FQPA have been consistent with its legislative intent. For example, some stakeholders raised concerns regarding EPA's application of the 10X Children's Safety Factor,[2] citing problems with the clarity and transparency of when and how 10X is retained, when it is reduced, and how these determinations are made. In 2000, GAO conducted a review to examine the approach EPA developed for making decisions in applying the FQPA Children's Safety Factor and the actual application of that factor.[3] Therefore, this issue will not be addressed by the OIG; application of the FQPA Children's Safety Factor falls under OPP's discretion to interpret the FQPA requirements.

Other stakeholders stated concerns over EPA's implementation of the cumulative exposure requirements and the use of interim reregistration eligibility decisions. Additionally, certain stakeholders expressed concerns over whether EPA has the data it needs to make decisions under the FQPA. This includes when to impose or reduce safety factors, data on developmental neurotoxicty, and information on cumulative and aggregate effects. Concerns related to data adequacy will be addressed in a subsequent OIG report. Other stakeholders noted that without sufficient data, it is difficult for EPA to measure its success in implementing FQPA and in ascertaining whether FQPA is making a substantive difference in children's health. Performance measurement will also be addressed in a forthcoming OIG report on the impact of FQPA.

[2] Specifically FQPA requires EPA to: ".....use an extra 10-fold safety factor to take into account potential pre- and post-natal development toxicity and completeness of the data with respect to exposure and toxicity to infants and children. A different safety factor may be used only if, on the basis of reliable data, such a factor will be safe for infants and children."

[3] GAO Report; GAO/HEHS-00-175: "Children and Pesticides: New Approach to Considering Risk is Partly in Place," September 2000.

# Chapter 3
## EPA Needs to Ensure Opportunities for Public Participation

Agency policy notes public consultation improves the quality and transparency of the Agency's decisions, and that it is essential that the public plays a major role in environmental decision making. However, OPP's use of public comment periods has varied by activity and over time. OPP allowed public comment periods when developing the Agency's major FQPA science policy papers, but there were limited formal public comment periods between 1996 and 2002, prior to the release of final pesticide reregistration eligibility decisions. EPA rectified this situation prior to the release of the final decision by a change in OPP policy effective in 2002. In 2004, OPP finalized the policy on public comment for pesticide registrations and reregistrations to allow at least one formal comment period, with the exception of pesticides classified as reduced risk. Also, the Agency listed in its 2004 policy the factors it considers in determining whether to use a four- or six-phase public participation process, but we believe the criteria for selecting the number of public comment periods should be more clearly defined.

### Importance of Public Participation in Implementing FQPA

Providing opportunities for public participation is an important vehicle for increasing transparency, improving decision making, and increasing overall public confidence. By including stakeholders and other members of the public in the process, EPA hopes to arrive at the fairest, most realistic, and most informed decisions possible. In an August 1993 memo to all employees, the EPA Administrator stated:

> *In all its programs, EPA must provide for the most extensive public participation possible in decision-making. This requires that we remain open to all points of view and take affirmative steps to solicit input from those who will be affected by decisions.*

A consent decree dated March 30, 2000, states the Agency's interest in providing opportunities for public participation in pesticide reregistration.[4] EPA reiterated that transparency of the Agency's regulatory decisions is an area of emphasis and importance in the Agency's Fiscal Year 2005 Annual Plan, and in EPA's May 14, 2005, Federal Register notice on the public participation process.[5] EPA states that

[4] Amended Partial Consent Decree Case No. C-99-3701 CAL.
[5] "Pesticide Tolerance Reassessment and Reregistration; Public Participation Process," Federal Register: May 14, 2004 (Volume 69, Number 94), Pages 26819-26823.

it is strongly committed to involving stakeholders and the public in its development of pesticide reregistration and tolerance reassessment decisions.

## EPA Solicited Stakeholder Involvement in Developing Papers

EPA recognized that building the scientific framework for implementing FQPA would require consultation with external scientists, and therefore utilized advisory committees. Since 1996, the Agency has developed multiple major science policy papers (see Appendix B) in collaboration with other Agency program offices and external representation from industry, environmental groups, and other interested entities. Public comment periods were held for all of the FQPA major science policy papers.

## Pilot Program Led to New Policy, but Further Guidance Needed

Although OPP finalized a policy for soliciting public comment under the pesticide reregistration process in 2004, the policy lacks criteria for clearly determining the level of review required for a particular pesticide. While the Agency does describe factors affecting the decision to offer one or two comment periods in the May 14, 2004, Federal Register Notice, it does not provide clear guidance as to which process to use for each instance. This leaves the process open to criticism from stakeholders.

As part of the Agency's ongoing FQPA implementation, EPA began conducting individual assessments of the organophosphate pesticides.[6] In 1998, the Agency developed a six-phase pilot reregistration process (see Table 3.1) for reviewing organophosphates which, according to Agency documents, would provide the public greater access to information about these pesticides. This would include EPA's preliminary risk assessments and risk management proposals. Organophosphate pesticides are currently registered under interim reregistration eligibility decisions, which cannot be finalized until publication of a final cumulative risk assessment for those pesticides. In our sample review, all eight interim decisions (including the seven organophosphates indicated in footnote 6) had the two required formal public comment periods.

Within 2 years after the initiation of the organophosphate pilot, EPA extended a similar public participation process to non-organophosphate pesticides undergoing tolerance reassessment and pesticide reregistration. On March 15, 2000, EPA published its proposed six-phase process for all pesticides scheduled for tolerance reassessment and reregistration; however, this policy was not finalized until the spring of 2004. According to OPP, the policy was largely in

[6] 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. The seven organophosphates within our sample which were also included in the pilot are: Disulfoton, Methyl Parathion, Oxydemeton-methyl, Pirimiphos-methyl, Profenofos, Propetamphos, and Terbufos.

place and being closely followed by 2002. This new policy increases opportunities for public participation in the development of pesticide risk assessments and risk management decisions. The steps listed in Table 3.1 are to be taken after OPP has assessed the potential hazards to human health and the environment.

**Table 3.1: Six-phase Public Participation Process for Tolerance Reassessment and Reregistration**

| Phase | Time Frame | Description |
|---|---|---|
| 1 | 30 days | **Registrant "Error Only" Review**<br>*Human health and ecological risk assessments are sent to registrants for error correction review.* |
| 2 | Up to 30 days | **EPA Considers Registrants' Comments**<br>*Errors identified by registrants are reviewed by EPA and corrected as appropriate.* |
| 3 | 60 days | **Public Comments on Risk Assessments and Risk Characterization**<br>*EPA publishes a Federal Register notice announcing availability of risk assessments and related documents from public docket and EPA's Web site.* |
| 4 | Up to 90 days | **EPA Revises Risk Assessments, Develops Preliminary Risk Reduction Options, and Considers Public Comments** |
| 5 | 60 days | **Public Comments on Risk Reduction**<br>*EPA publishes a Federal Register notice announcing availability of revised risk assessments and response to the initial public comments received. EPA also releases and invites formal public comments.* |
| 6 | Up to 60 days | **EPA Develops Final Risk Management**<br>*EPA considers public comments from previous phase and develops risk management decision. The final or interim reregistration eligibility decision is released.* |

The new policy on public participation offers a four-phase alternative process that could be used in some situations that would allow for one opportunity for public comment prior to issuance of a decision (see Table 3.2).

**Table 3.2: Four-phase Phase Public Participation Process for Tolerance Reassessment and Reregistration**

| Phase | Time Frame | Description |
|---|---|---|
| 1 | 30 days | **Registrant "Error Only" Review**<br>*Human health and ecological risk assessments are sent to registrants for error correction review.* |
| 2 | 30-60 days | **EPA Considers Registrants' Comments**<br>*Errors identified by registrants are reviewed by EPA and corrected as appropriate.* |
| 3 | 60-90 days | **Public Comments on Risk Assessments and Preliminary Risk Reduction Options**<br>*EPA publishes a Federal Register notice announcing availability of risk assessments and preliminary risk reduction options for formal public comment.* |
| 4 | Up to 90 days | **EPA Develops Final Risk Management**<br>*EPA considers public comments received, risk management ideas, and proposals received during previous phase to develop risk management decision. The final or interim reregistration eligibility decision is released.* |

The various options for public comment give OPP the flexibility to consult with stakeholders and obtain public input as needed while still making timely decisions and meeting statutory goals and deadlines. Although the reregistration process has clearly defined opportunities for public comment, the Federal Register notice announcing the final reregistration processes does not articulate what method (six-phase or four-phase) the Agency should use for any particular pesticide or pesticide class.[7] OPP officials indicated the selection method is determined on a case-by-case basis, generally based on past experience. The six-phase process provides more opportunities for public comment than the four-phase process, and the lack of clear selection guidance potentially leaves the process determination open to criticism from outside stakeholders.

## New Policy Increased Opportunities for Formal Public Comment

A consistent lack of formal public comment opportunities prior to the release of final reregistrations issued between 1996 and 2002 was rectified by the change in OPP policy in 2002.[8] We reviewed 35 percent (21 decisions) of the universe of 60 post-FQPA completed final reregistration eligibility decisions. We found that only 19 percent (4 decisions) of the decisions reviewed had some formal public comment period prior to the issuance of the reregistration—all decided after the implementation of the new policy (see Table 3.3 and Appendix C). Similarly, we reviewed one third (8 total) of the universe of 24 post-FQPA interim reregistration eligibility decisions and found that all of these decisions had formal comment periods prior to the issuance of the interim decision in accordance with the new policy.

Table 3.3 illustrates that prior to OPP's policy change, all final decisions reviewed had no formal public comment opportunities prior to publication. However, of the decisions reviewed that were finalized after the 2002 policy change, we found that all had one or more public comment opportunities in 2002 and subsequent years.

[7] "Pesticide Tolerance Reassessment and Reregistration; Public Participation Process," Federal Register: May 14, 2004 (Volume 69, Number 94), Pages 26819-26823.

[8] OPP provided a table demonstrating the impacts of the 2002 public involvement policy. As a result of the policy change, all 26 reregistration eligibility decisions and 11 interim reregistration eligibility decisions, except those for low-risk pesticides, received either one or two public comment periods prior to the publication of the final reregistration eligibility decisions or interim reregistration eligibility decisions.

**Table 3.3: Public Comment Opportunities for Reregistrations**

| Sample of Final Reregistration Eligibility Decisions | Number of Opportunities for Formal Public Comment | | |
|---|---|---|---|
| | Two | One | None |
| 1996 | 0 | 0 | 1 |
| 1997 | 0 | 0 | 7 |
| 1998 | 0 | 0 | 4 |
| 1999 | 0 | 0 | 3 |
| 2000 | 0 | 0 | 2 |
| 2001 | 0 | 0 | 0 |
| 2002 | 0 | 1 | 0 |
| 2003 | 0 | 1 | 0 |
| 2004 | 0 | 2 | 0 |
| Total Final Reregistration Eligibility Decisions | 0 | 4 | 17 |

We recognize that OPP published a final policy on public involvement in May 2004, as previously discussed; FQPA implementation, however, began in 1996. According to OPP officials, even though the policy was not finalized until May of 2004, they began implementing the proposed public participation requirements in 2002. However, Agency documents show that many reregistration decisions were completed prior to implementation of the new policy. According to Agency reports, for example OPP had reassessed 3,290 tolerances by July 30, 1999. Of the reassessments completed, 66 percent (2,178) were in the first, or the highest risk, priority group. Although this represents significant progress for OPP in the pesticide reregistration process, it indicates that a majority of the pesticide decisions up to that point were made prior to finalizing and implementing the new public involvement policy.

## Recommendations

We recommend that the Director of the Office of Pesticide Programs:

3-1 Continue to allow for at least one public comment period prior to the issuance of a final reregistration eligibility decision. We recommend that OPP provide written justification for deviating from the six-phase process.

3-2 Develop further guidance to demonstrate to the public which version of the public participation process OPP selects, and make this information readily accessible on their website.

## Agency Response and OIG Evaluation

The Agency agreed in general to the recommendations provided in Chapter 3 and the overall message that it needs to ensure ample opportunities for public

participation. However, the Agency believed that the report does not take into account the expansion of the amount of public participation provided and is thus misleading in its description of OPP's public participation procedures.

The Agency commented that "if the analysis focused on approved reregistration eligibility decisions since OPP began to routinely use its voluntary public participation process, the results would be different." However, Agency documents show that many reregistration decisions were completed prior to the new policy ensuring public participation, and these decisions remain in effect. Moreover, FQPA requires EPA to give highest priority to pesticides that appear to pose the greatest risk. Our conclusions on OPP's post-FQPA public participation efforts in reregistration decisions were based on review results from a statistically valid sample of completed reregistration decisions from FQPA's passage (October 1996) until the present day (February 28, 2005). The sampling universe and sampling methodology are fully explained within Chapter 1.

In its comments to the draft report, the Agency did not agree with our use of formal comment periods as exclusive indications of public participation. While we recognize that there are other modes of public participation, including the examples provided in the Agency's response, we believe the use of formal public participation comment periods is a key method for the Agency to ensure that all interested stakeholders have a chance to review and comment on the proposed reregistration decision.

Although the Agency agreed with Recommendation 3-2 concerning guidance with the pesticide reregistration process (the six-phase or four-phase process), OPP believed that the draft report overstates the importance of setting additional criteria and fails to give credence to the Agency's current policy. We recognized in the report that OPP has such as policy in place; however, it is our position that guidance is needed to ensure that decisions about the frequency of public participation cannot be perceived to be arbitrary.

Appendix A provides the full text of the Agency's response, while additional attachments to that memorandum are available at http://www.epa.gov/oig/reports/2006/20051019-2006-P-00003A.pdf. Appendix B provides more detailed OIG comments on the Agency's response.

# Chapter 4
# Additional Opportunities Exist to Enhance Public Confidence

We identified the following areas where guidance is still needed to address shortcomings and improve public confidence:

- Gathering data to identify and assess additional major subgroups of consumers for the pesticide decision making process; and
- Responding promptly and directly to petitions and requests from external stakeholders.

Generic resolution of science and policy questions through the development of guidance documents puts the public on notice of the way the Agency plans to resolve future questions of the same general substance. Guidance also helps broaden opportunities for public participation in policymaking and helps prevent the appearance of arbitrary decisions. OPP needs to respond promptly to external petitions and requests to increase public confidence. Responding promptly and directly to petitions and requests from external stakeholders will improve public confidence in OPP's work.

## Additional Information Necessary to Identify and Assess Major Subgroups

Stakeholders expressed concerns that OPP's current dietary and nondietary risk assessment processes do not sufficiently protect major identifiable subgroups of consumers. For example, some stakeholders noted that OPP lacks information regarding the consideration of certain non-dietary exposure pathways for subgroups, including take-home and spray drift exposures from pesticides. Other stakeholders indicated that OPP also lacks dietary exposure information for a number of racial minority subgroups.

GAO recommended in 1989 that EPA establish a policy concerning whether, and/or in what circumstances, tolerance decisions are to be based on the most highly exposed subgroup(s).[9] Furthermore, concerns over the protection of subgroups culminated in a 2003 lawsuit against the Agency by a coalition of environmental and public health groups with regard to the designation of farm children as a major identifiable subgroup. This lawsuit was subsequently dismissed for a lack of jurisdiction.

[9] GAO Testimony to the Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives; GAO/T-RCED-89-35: "Guidelines Needed for EPA's Tolerance Assessments of Pesticide Residues in Food," May 1989.

Among the changes to the Agency's processes required by FQPA was the consideration of available information on the aggregate exposures, variability of sensitivities, and dietary consumption patterns of major identifiable subgroups of consumers. Specifically, Section 405 states:

> **SEC. 405. TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES**
>
> "(D) FACTORS.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—
>
> ''(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);
>
> ''(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non- occupational sources;
>
> ''(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers...."

OPP has traditionally used a dietary exposure model known as the Dietary Exposure Estimation Model (DEEM) to assess pesticide exposures. According to OPP officials, the DEEM system examines 27 different subgroups based on age, region, and race. In evaluating residential exposures, OPP officials said that four additional subgroups are examined, including toddlers, youth, young adults, and applicators. According to OPP, almost all of the subgroups included in the DEEM and other exposure models were considered by OPP prior to the passage of FQPA. Nevertheless, there is still controversy as to whether additional subgroups should be examined.

### *Actions Taken to Protect Subgroups*

In addition to considering the aforementioned subgroups for its dietary risk and residential assessments, OPP indicated that it considered additional subgroups on a case-by-case basis if it believed the additional subgroup might potentially receive greater exposure than one of the standard subgroups. OPP provided nine examples of decisions where specified subgroups were taken into consideration in the decision-making process. While OPP considered subgroups in the decision-making process for the examples provided, we found that OPP determined that no further action was deemed necessary to protect subgroups in five of the nine examples provided.

Three of the nine examples involved subgroups in addition to the standard subgroups. OPP concluded that these additional subgroups did not face a risk of concern that required additional risk mitigation or for which additional data were necessary and did not exist. Consequently, OPP's consideration of the additional subgroup in these three examples did not lead to a change in tolerance levels or

provide other steps to protect these subgroups in the final reregistration eligibility decisions.

Of the nine examples provided by OPP, three were instances where consideration of risks to children's subgroups did result in OPP attempting to take action to protect children or address a regional subpopulation. For example, OPP took significant action to protect infants and children from the risks posed by organophosphate pesticides, including diazinon and chlorpyrifos, through the cancellation of certain product uses.

Additional information on OPP's measures of success in terms of the pesticide registration and reregistration programs is planned for a subsequent OIG report. The ninth example, the cumulative risk assessment of the organophosphate pesticides, is not yet finalized. Details on the nine examples are in Table 4.1.

**Table 4.1: Actions Taken to Protect Subgroups in Examples Provided by OPP**

| Pesticide | Subpopulation | Exposure Pathway | Actions to Protect Subgroups |
|---|---|---|---|
| Lindane | Alaskan Native Subpopulation | Dietary | None; increased exposure to subgroups found not to cause risk of concern. |
| Cumulative risk assessment for organophosphates | Regional variations | Drinking Water | None; not yet final. |
| Triclopyr | Pregnant females, Native Americans in California | Dietary | None; increased exposure to subpopulation found not to cause risk of concern. |
| Zinc Phosphide | Children who eat rat poison | Oral (accidental ingestion) | Although found risk of concern to subpopulation, formulation changes did not occur as recommended. |
| Fenamiphos | Regional variations | Drinking Water | Registrant cancelled all uses. |
| Propargite | San Joaquin-Tulare study unit | Drinking Water | None; increased exposure to subpopulation found not to cause risk of concern. |
| Risk Assessment Process Changes | Age groups of children | Dietary | None (policy change). |
| Diazinon | Age groups of children | Dietary and residential | Residential uses cancelled, some crop uses restricted. |
| Chlorpyrifos | Age groups of children | Dietary and residential | Residential uses cancelled, some crop uses restricted. |

### *Additional Data Needed*

We found additional data are needed for the identification of subgroups potentially more highly exposed to pesticides, particularly those via non-dietary pathways. OPP officials noted that the identification of subgroups is complicated and requires additional information and research. OPP examined the different consumption patterns among children based on age-related subgroupings. In aggregating exposure, OPP sums both dietary exposures and non-dietary exposures for an age group when that is appropriate given a pesticide's use. EPA's Office of Research and Development (ORD) conducts research on susceptible and highly exposed life stages and subgroups. As part of this research, subgroups may be based on regional, life stage, gender, background, health status, and dietary variations. According to ORD's Strategy for Environmental Risks to Children, the examination of subgroups hypothesized to be highly exposed, including special groups such as children living on farms, is a high priority area.

Working with ORD to develop a research agenda related to the protection of subgroups would be an opportunity for OPP to gather necessary data to protect subgroups under FQPA. However, before gathering this information, OPP needs a prescribed methodology for considering additional subgroups. OPP also needs a strategy for collecting and disseminating information about subgroups. OPP should work with ORD to prioritize and develop a research agenda on subgroups for use in pesticide registrations and reregistrations under FQPA.

## OPP Should Respond Promptly and Directly to Stakeholder Petitions

Stakeholders expressed concern that OPP did not respond promptly to petitions and requests. We are aware of three petitions where the Agency's response could be perceived as not being timely, direct, or transparent. In one case, for a petition filed by the Natural Resources Defense Council (NRDC), we found that it took EPA 6 years to respond. The response to this petition was incorporated into another policy decision and not addressed directly to the petitioners involved. We also found EPA failed to respond in a clear and transparent manner to petitions filed by external stakeholders concerning the 10X children's safety factor[10] and on the wood preservative copper chromatic arsenic.[11] We believe that OPP should respond to petitions and requests from external stakeholders within a reasonable amount of time and in a direct manner.

[10] NRDC, et. al. *Petition to the Administrator, U.S. Environmental Protection Agency*. Petition for a directive that the agency fulfill its duty to retain the child-protective tenfold safety factor mandated by the Food Quality Protection Act. Filed April 23, 1998.

[11] Beyond Pesticides, et. al. *Petition For Suspension and Cancellation of Creosote.* Petition for the Administrator of the Environmental Protection Agency (EPA) to issue a Notice of Intent to Cancel the registration of the wood preservative creosote pursuant to Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Filed February 26, 2002.

### *OPP Should Respond Promptly to Stakeholder Petitions*

One concern arose over the lack of response to petitions filed with the Agency under the Administrative Procedure Act (APA).[12] In 1998, the NRDC petitioned EPA under the APA to consider, among other issues, farm children as a major identifiable subgroup as defined by the FQPA. According to OPP, it issued a response to NRDC's 1998 Farm Children Petition as part of a ruling in the Federal Register on objections filed concerning Imidacloprid tolerances.[13] However this was not issued until May 2004, 6 years after NRDC's petition. NRDC received direct notice on August 23, 2005, from OPP that the Imidacloprid ruling served as a response to the Farm Children petition, 1 year after the publication of the decision in the Federal Register.

While there are no formal Agency regulations or procedures that prescribe the manner and timing of the Agency's response to an APA petition like NRDC's, we found that the U.S. Court of Appeals, District of Columbia Circuit, held in a June 2004 decision that, under the APA, a Federal agency is obligated to conclude a matter presented to it within a reasonable time.[14] According to the Circuit Court opinion, "While there is no *per se* rule as to how long is too long to wait for agency action, a reasonable time for agency action is typically counted in weeks or months, not years." The court ruled that under the circumstances in that case, the 6-year-plus delay in the case considered was "nothing less than egregious."

OPP acknowledged that its response time to petitions has in some instances been lengthy, but argued that the reasonableness of the timing of its response should balance other factors, including OPP's statutory obligations under the FQPA. We believe that OPP should respond to petitions and requests from external stakeholders within a reasonable amount of time. The 6 years it took OPP to respond to the Farm Children Petition is inconsistent with OPP's stated policies on openness and transparency. Ultimately, it would be up to a court to undertake the complex balancing of factors to determine if OPP's response was unreasonable delayed. Nonetheless, OPP's response is contrary to one of its published policies, the Public Involvement Policy from May 2003.

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[12] The Administrative Procedure Act, 5 United States Code 553, The APA, enacted in 1946, established procedures which federal agencies must follow in the development and issuance of regulations and in the procedures to be used for adjudications. The Attorney General guidance to implement the APA states that the basic purposes of the APA are:

1) To require agencies to keep the public informed of their organization, procedures and rules;
2) To provide for public participation in the rulemaking process;
3) To establish uniform standards for the conduct of formal rulemaking and adjudication; and
4) To restate the law scope of judicial review.

[13] "Imidacloprid; Order Denying Objections to Issuance of Tolerance," Federal Register: May 26, 2004 (Volume 69, Number 102), pages 30041 - 30076.

[14] *In Re: American Rivers and Idaho Rivers United*. United States Court of Appeals, District of Columbia Circuit. No. 03-1122, argued March 16, 2004, decided June 22, 2004.

### *OPP Should Respond Directly to Stakeholder Petitions*

We also urge EPA to respond to petitions in a more direct manner. For example, the title of the Federal Register ruling on Imidacloprid contains no mention of the NRDC Farm Children Petition and NRDC was not immediately mailed a copy of the ruling.[15] Additionally, in response to the aforementioned stakeholder concerns, OPP said that it responded to petitions concerning the children's safety factor and aggregate exposure in the context of the science policy papers and response to comment documents on those topics. According to OPP, they are addressing the copper chromatic arsenic petition in the context of its ongoing effort to make a reregistration determination on wood preservatives.

OPP stated that the petitions it has received have frequently raised either broad policy issues or a combination of policy issues and detailed scientific questions. OPP explained that because of the high resource demands posed by the completion of the FQPA tolerance reassessment program, it has frequently dealt with petitions by folding the response to them into more generalized actions in support of tolerance reassessment or other required actions that are part of the tolerance program. OPP stated that it believes this approach has the added benefit of including its response to petitions in widely-disseminated public documents so that all interested parties would be aware of OPP's decision. While this has allowed OPP to allocate its resources in a manner it considers most likely to achieve its highest FQPA priority, it has also decreased stakeholder confidence in and the transparency of OPP's processes.

Although we understand the benefit to OPP of incorporating petition responses into other public documents, it would require little for OPP to additionally provide direct personal notice to petitioning parties. Such notice is appropriate for parties who have submitted petitions. Responding to petitions and requests from external stakeholders in a prompt and direct manner will enhance public participation, transparency, and clarity.

## Recommendations

We recommend that the Director, Office of Pesticide Programs:

4-1 Develop guidance that provides a defined methodology for identifying additional subgroups in a systematic manner, as well as a strategy for collecting and disseminating information about subgroups. Continue to work with ORD to develop a research agenda focusing on exposures to major identifiable subgroups.

4-2 Respond to petitions and requests from external stakeholders as promptly as possible given statutory obligations. All responses to petitions should

[15] See footnote 11.

be directly communicated to petitioners. Develop a policy that stresses the importance of Agency response to external comment in a timely manner.

## Agency Response and OIG Evaluation

The Agency agreed in general to the recommendations provided in Chapter 4. However, the Agency provided numerous comments regarding the accuracy and presentation of the narrative within the report preceding the recommendations. We added clarification and made corrections as deemed necessary. We stand by the remainder of our facts.

In response to OIG Recommendation 4-1, the Agency stated that the OIG does not explain what it means by a "defined methodology for identifying additional subpopulations in a systematic manner." We believe it is imperative that the Agency first have a methodology in place describing at a minimum how it will identify additional subgroups on a case-by-case basis. We recommend that OPP document the methodology by which it currently considers additional subgroups that might potentially receive greater exposure than one of the standard subgroups.

The Agency agreed with the recommendation to develop a strategy for collecting and disseminating information about subgroups. In response to the recommendation for OPP to continue to work with ORD to develop a research agenda focusing on exposures to major identifiable subgroups, OPP acknowledged the value of such collaboration. Specifically, OPP plans to continue to work with ORD to develop a research agenda that seeks to identify meaningful exposures to pesticide residues.

In responding to OIG Recommendation 4-2, the Agency stated that, "we agree with the spirit of the recommendation that petitions should be responded to in a timely manner and we would admit that we have been frustrated that it has taken an extensive period of time to address some FQPA petitions." The Agency stated that the conclusions drawn by the OIG were "devoid of any legal reasoning." We conducted a policy, not a legal, analysis of these decisions. We determined that the responses by OPP to the petitions in question are inconsistent with the intent of Agency policy regarding transparency. We believe that OPP should take additional steps to communicate directly to the petitioners as a means to increase clarity and public confidence. According to the Agency's response, it "will consider such steps to further transparency."

Appendix A provides the full text of the Agency's response, while additional attachments to that memorandum are available at http://www.epa.gov/oig/reports/2006/20051019-2006-P-00003A.pdf. Appendix B provides more detailed OIG comments on the Agency's response.

**Appendix A**

# *Agency's Response*

**MEMORANDUM**

**SUBJECT:** Draft Evaluation Report:
Changes Needed to Improve Public Confidence in EPA's Implementation of the Food Quality Protection Act
Assignment No. 2004-001191

**FROM:** Jim Jones
Director, Office of Pesticide Programs

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

Thank you for the opportunity to comment on the draft evaluation, dated [June 23, 2005, and amended on] September 2, 2005, by the Office of Inspector General on EPA's Implementation of the Food Quality Protection Act (FQPA). The Office of Pesticide Programs (OPP) appreciates the Office of Inspector General's effort to understand OPP's legal and regulatory framework and OPP's procedures for processing pesticide registrations and reregistrations to implement the provision of FQPA.

In general, we agree with many of the recommendations provided in the report because they reflect how we have been consistently performing. However, as will be discussed in this response letter, we are concerned in the way OPP's performance has been characterized in the text of the report. We will provide specific examples illustrating inaccuracies and mis-representations throughout our response.

## I. Introduction to OPP's Response to OIG's Report

Historically, OPP regulates pesticides under two major federal statutes. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), OPP registers pesticides for use in the United States and prescribes labeling and other regulatory requirements to prevent unreasonable adverse effects on health or the environment. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), OPP establishes tolerances (maximum legally permissible levels) for pesticide residues in food. Tolerances are enforced by the Department of Health and Human Services/Food and Drug Administration (HHS/FDA) for most foods, U.S. Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) for meat, poultry, and some egg products.

FQPA amended both major pesticide laws to establish a more consistent, protective regulatory scheme, grounded in sound science. It mandated a single, health-based standard for all pesticides in all foods. It also provided special protections for infants and children; expedited the approval of safer pesticides; created incentives for the development and maintenance of effective crop protection tools for American farmers; and required periodic re-evaluation of pesticide registrations and tolerances to ensure that the scientific data supporting pesticide registrations will remain up to date in the future.

The EPA was directed by then Vice President Gore to ensure that implementation of the law was based on four key principles: the use of sound science in protecting public health; the use of an open, transparent process for decision-making; the allowance of a reasonable transition for agriculture; and the establishment of an effective means of consultation with the public and other agencies.

The EPA's OIG draft report "Changes Needed to Improve Public Confidence in EPA's Implementation of the Food Quality Protection Act" focuses upon the following issues: whether OPP allows for public comment and participation in the pesticide decision-making process; and what methodology OPP has in place to address: (a) major identifiable subgroups of consumers; and (b) OPP's responsiveness to petitions received from external stakeholders.

OIG's recommendations and OPP's comments on the draft report and the recommendations are below.

## II. **Chapters 1 and 2 - Introduction to the Report, Pesticide Regulation, and FQPA**

The first two chapters of the report provide background on the scope and methodology of the report and on FIFRA and FQPA generally. We appreciate OIG's effort in meeting with a variety of stakeholders to gain their perspectives upon FQPA implementation.

In addition, OIG's draft report recognizes OPP's work to set the implementation of FQPA's requirements in motion, finding that "OPP Made Substantial Changes as a Result of FQPA." FQPA's new safety standard required changes in pesticide risk assessment methods and science policies. As OIG's report notes, "Key to implementing FQPA's science provision was the effort OPP made in developing science policy papers."

## III. **"Chapter 3 - EPA Needs to Ensure Opportunities for Public Participation**"

OPP agrees that we need to ensure ample opportunities for public participation and that we do so in accordance with the Agency's Public Involvement Policy (2003) and our own public participation policy (2004). OIG concluded that OPP actively solicited stakeholder involvement in developing the science policy papers, utilizing advisory committees, and collaborating with other EPA offices, and representatives from industry, environmental groups, and other interested external stakeholders. OPP held a large number of public meetings, including the meetings of

the Tolerance Reassessment Advisory Committee (TRAC) and the Committee to Advise on Reassessment and Transition (CARAT) to ensure active stakeholder involvement in the development of the science policies. However, OIG mis-characterizes OPP's public participation efforts in reregistration decisions since FQPA's passage and inaccurately concludes that OPP has not consistently solicited public participation. OPP disagrees with this conclusion and will discuss how public participation has been a vital component of the Agency's pesticide regulatory program.

**See OIG Comment in Appendix B, Note 1**

**III.A. OIG Recommendation 3-1:**

**"Continue to allow for at least one comment period prior to the issuance of a final registration or reregistration eligibility decision. OPP should provide written justification for exceptions to the public comment policy, including for low-risk pesticides omitted from the public participation process.**"

**OPP Response:**

OPP agrees that we need to allow for at least one comment period prior to the issuance of a final reregistration eligibility decision (RED). The reregistration public participation process that OPP has been using for all reregistration actions for the last few years and intends to use through the completion of reregistration is, with one justifiable exception, fully consistent with this recommendation and the Agency's Public Involvement Policy. In brief, OPP's policy since early 2000 is to hold at least one public comment period for chemicals being reviewed under the reregistration process. As a result, by 2002 at least one comment period was provided prior to the signature of all REDs, with the sole exception of REDs on pesticides judged to be of low-risk.

OPP has always allowed for some public participation in the reregistration/tolerance reassessment program. The amount and timing of public participation has evolved over the years as OPP has gained experience with the program. Importantly, several years ago OPP implemented its current public participation process which includes pre-signature public comment periods for REDs for all pesticides except those posing low risk. Because the draft OIG Report does not take into account that the amount of public participation has expanded and the timing of such participation has been moved earlier in the process, the Report presents a highly misleading description of OPP's public participation procedures. Below, we trace the evolution of our public participation procedures and point out how the analysis in the draft OIG Report errs in describing the percentage of REDs that currently receive pre-signature public comment periods.

**See OIG Comment in Appendix B, Note 2**

**Background on Reregistration Public Participation**

With the enactment of FQPA, the need for extensive broad public involvement was clear because the first group of pesticides reviewed under FQPA had risk concerns and generally were efficacious and economical. The need for enhanced involvement, in combination with the Vice President's memo directing public involvement in food quality protection, lead to the formation of a formal Federal Advisory Committee Act (FACA) committee, the TRAC, in early 1998.

Based on the input received from this committee, OPP began the Pilot Public Participation Process for the organophosphate (OP) pesticides. This pilot process included numerous pre-signature opportunities for public comment. Given the success of the OP pilot process, OPP chose to expand the process to all reregistration decisions and issued notice of the proposed public participation process in the *Federal Register* in 2000 (March 15, 2000; 65 FR 14199). Although the proposed process recognized that the amount of public process should vary based on the pesticide involved, at a minimum, the proposed process included at least one pre-signature public comment period for all pesticides save those presenting the lowest risks. This process was largely in place and being closely followed by 2002, although it was not formally finalized until 2004. The finalized procedures provided for a full and a modified public participation process to enable OPP to tailor the level of review to the level of risk, use, complexity and public concern associated with each pesticide.

On May 14, 2004, OPP published in the *Federal Register*: "Notice – Pesticide Tolerance Reassessment and Reregistration; Public Participation Process." An overview of the different public participation processes is described at Attachment 1.

**New Public Participation Process Affords Flexibility Appropriate to Individual Pesticide Decisions**

By May 2004, when the Agency finalized its public participation process with several more years of reregistration experience, it had became clear that differences in the complexity of individual pesticide decisions required a more flexible public participation process. Although initially conceived as a six-phase process, for some decisions a shorter process afforded ample opportunity for public participation while shortening the decision time. The final process is designed to provide the Agency the flexibility to make judgments regarding the number and timing of public comment periods and to modify the process on a case-by-case basis. Even though the one-phase process used for low risk chemicals is conducted following signature of the RED, this process still provides an opportunity for public comment that can affect the final action. If the Agency receives a comment that may affect the RED decision, the comment is evaluated and the RED is amended, as appropriate.

Currently, all conventional chemicals undergo either the original six-phase process for the most complex decisions, the four-phase process for less complex decisions, or a single phase process for pesticides posing little or no risk concerns.

Biochemical/microbial pesticides are by definition low-risk, and are almost exclusively accorded the single phase process. Antimicrobial pesticide chemicals may fall within the six-phase, four-phase, or one-phase processes, depending on their characteristics. The most complex set of these pesticides–the wood preservatives–are currently undergoing reregistration using the six-phase process.

In addition to providing formal comment periods, the reregistration process continues to include significant informal outreach opportunities to a range of stakeholders throughout the process.

**Comments on OIG Analysis and Conclusions on Past Decisions**

The OIG reviewed a random sample of 29 reregistration eligibility decisions (REDs and Interim REDs (IREDs)) from December 1996 to September 2004. The analysis shows that all eight of the Interim REDs surveyed had formal public comment periods prior to signature. It also shows that of the 21 REDs surveyed, four had formal comment periods prior to signature. Based on the analysis, the OIG concludes that OPP has not consistently solicited public participation. Even though OIG's analysis included these 29 decisions, Table 3.3 does not reflect the Interim REDs, ***all*** of which featured two formal public comment periods. This omission suggests that the Agency provided fewer opportunities for public participation during this time period.

**See OIG Comment in Appendix B, Note 3**

The preliminary risk assessment process for most of the decisions surveyed was completed prior to OPP adopting the more formalized public participation process for all reregistration actions. If the analysis focused on approved REDs since OPP began to routinely use its voluntary public participation process, the results would be very different. Of the 26 REDs issued for conventional pesticides from 2002 through 2004, eighteen had two comment periods (six-phase process) and five had one comment period (four-phase process) prior to the signature of the RED. The remaining three were low-risk chemicals with a formal comment period on the RED after signature.

**See OIG Comment in Appendix B, Note 4**

The OIG analysis relies on "formal comment" periods as exclusive indications of public participation and does not reflect the significant public outreach involved in many of the decisions. Most reregistration decisions routinely included public outreach activities prior to the RED signature. For example, in developing the diuron reregistration decision, OPP consulted with state governments, utility companies, growers, and paint manufacturers. Both the terrazole and chlorothanil decision process included input from golf course superintendents, as well as other interested parties. The consultations mentioned here are a few examples of the types of stakeholder involvement efforts associated with making reregistration decisions. Unless the chemical had negligible risk concerns, OPP has routinely consulted with major stakeholder groups prior to making its reregistration decision.

**See OIG Comment in Appendix B, Note 5**

In other cases, the RED itself announced a public involvement process. In another example, OPP announced the initiation of an extensive public process for the Aluminum Phosphide RED. Although the RED was signed, the Agency solicited public comment and modified its decision based on that public input. The same is true for chlorophacinone and diphacinone that were part of the 1997 Rodenticide Cluster RED. Again OPP announced the formation of a public process for informing the Agency. In this instance, the Agency convened a year-long advisory subcommittee and took advice concerning young children and the potential for accidental exposure to rodent control pesticides.

**See OIG Comment in Appendix B, Note 6**

In fact, all the REDs surveyed by OIG actually provided a formal comment period after the RED was signed, but before the RED was implemented. For example, in the case of oxyfluorfen and MCPA [(4-chloro-2-methylphenoxy)acetic acid], the Agency received comments in response to the REDs that led OPP to amend both REDs.

Similarly, new tolerances, including those for new uses of existing pesticides, are established pursuant to the procedural rulemaking requirements in FFDCA section 408 which provides for a public comment period. Since such decisions may require an aggregate exposure assessment in order to make the safety finding under FFDCA, OPP has used such decisions as a reassessment determination for a pesticide's tolerances. The public comment period provided for setting new tolerances is relevant to your analysis of opportunities for public comment on tolerance reassessment decisions. In fact, a significant number of tolerance reassessment decisions (approximately 19% to date) have been made using this tolerance-setting rulemaking process and have provided an opportunity for pre-release public comment.)

Given the variety of public participation methods employed by OPP, the section heading in Chapter 3, “No Formal Public Comment Periods Found Prior to 2002," does not accurately reflect the scope and breadth of our public participation efforts prior to 2004. Since FQPA, OPP has conducted extensive public involvement efforts.

**See OIG Comment in Appendix B, Note 7**

Finally, OPP would like to note that we believe the term “registration” in the text of the OIG Recommendation 3-1 is a typo since a “registration eligibility decision” does not exist.

**III.B. OIG Recommendation 3-2:**

**“Develop guidance to determine which pesticide reregistration process (the six-phase or four-phase process) should be implemented on individual pesticide reregistration eligibility decisions.”**

**OPP Response:**

The draft report overstates the importance of setting additional “criteria” for conducting public participation in OPP’s reregistration program and neglects the Agency’s current policy on

public involvement by suggesting that further criteria are necessary for conducting legitimate public participation (see *Public Involvement Policy of the EPA*, May 2003, EPA-233-B-03-002). OPP's factors for determining the level of public participation are completely consistent with the 2003 Agency policy on public involvement. That policy instructs the methods for public involvement, "may take a variety of forms, depending on the issues to be addressed, the timing of the decision-making action, and the needs and resources of the interested and affected public." Such flexibility has been incorporated into the OPP policy and articulated by the various factors for determining whether a reregistration case is conducted by a one-, four-, or six-phase process.

**See OIG Comment in Appendix B, Note 8**

**OPP's May 2004 notice on the public participation process clearly describes and is completely consistent with the Agency's Public Involvement Policy. The notice describes the factors for determining whether a chemical goes through a one-, four- or six-phase process.** The factors include the magnitude of risk identified in the preliminary risk assessment, the degree of uncertainty in the preliminary assessment, the existence of unusual issues pertinent to the risk assessment and the level of public interest. When the Agency began using the process for conventional chemicals (specifically the organophosphates), it made virtually all RED decisions following the full six-phase public participation process. All REDs and IREDs completed in FY 2002 involved the six-phase process. Over time and with experience, OPP received very few comments for some draft REDs during a second public comment period. OPP concluded that for certain pesticides, an additional comment period would be of little, if any, value to the decision. Therefore, it would be an inefficient use of resources and unnecessarily delay OPP's and the registrants' implementation of any newly required risk mitigation measures to protect the public's health and/or the environment. Consequently, by 2004, OPP was able to provide adequate public comment and save resources by using the modified four-phase or one-phase processes. The Agency's website shows the planned comment periods for the next six months. However, the plan may change over time for specific pesticides, based on public comment and the results of OPP's preliminary risk assessments.

In the May 2004 notice, the basic framework for using different length public processes was given as, "level of risk, extent of use, overall complexity of the issues, and amount of public concern associated with each individual pesticide." The Agency outlines the factors for using the four-phase process as applying in a case of a pesticide having, "highly refined risk assessments, limited use, low risk concerns, few complex issues, and/or low public interest." In clarifying the conditions for the one-phase process, the Agency further carefully elaborated on the factors and meaning of low-risk pesticides as those that, "pose no or few risk concerns . . . [or] show low levels of (non-target) toxicity and/or pass through screening models and show very low levels of risk . . . [or] do not raise complex issues or public concerns."

## IV. "Chapter 4 - Additional Opportunities Exist to Enhance Public Confidence"

In Chapter 4 , OIG focused upon OPP's guidance on involving the public in FQPA related processes and decisions. They identified two areas where they stated that guidance is needed: gathering data to identify and assess major subgroups of consumers; and responding

promptly and directly to petitions and requests from all external stakeholders**.** OPP's responses to the recommendations in Chapter 4 are provided below.

**IV.A. OIG Recommendation 4-1**:

**"Develop guidance that provides a defined methodology for identifying additional subpopulations in a systematic manner, as well as a strategy for collecting and disseminating information about subgroups. Continue to work with ORD to develop a research agenda focusing on exposures to major identifiable subgroups."**

**OPP Response:**

OPP plans to continue to work with ORD to develop a research agenda that seeks to identify meaningful exposures to pesticide residues. That information is important to OPP in carrying out its responsibility to ensure that pesticide tolerances provide a reasonable certainty of no harm to consumers and major identifiable subgroups of consumers.

**See OIG Comment in Appendix B, Note 9**

The OIG report does not explain what it means by "a defined methodology for identifying additional subpopulations in a systematic manner." OPP is unwilling at this time to commit to developing such a methodology without an understanding and agreement of this recommendation. Moreover, given the multitude of factors involved in risk assessment under the FQPA, OPP is concerned that any such methodology that did much more than merely restate the statutory factors relevant to major identifiable subgroups – e.g., "dietary consumption patterns," "aggregate levels of exposure," and "variability of sensitivities" – would run the risk of inadvertently excluding critical information about a major identifiable subgroup. Instead, we think we should proceed by considering any and all available information that might define a subgroup and that might provide insights into differences in dietary consumption, aggregate exposure, or sensitivity. The approach to such an analysis and the conclusions reached would depend on the type of data available, which will vary from case to case. The numerous examples that we provided to the OIG illustrate a range of ways in which we have approached this responsibility. OPP agrees with the OIG that we should be transparent in our explanation of our decisions whether or not a particular group is a "major identifiable subgroup" and provide for public comment opportunities on our decisions. We also agree that these decisions should be based on consistent principles and reflect sound science and we believe we have and continue to be transparent by inviting and including public input.

Although the draft report attempts to describe OPP's risk assessment process for consumers, including major identifiable subgroups of consumers, several significant problems are evident. First, the Report appears to present stakeholders' concerns as fact, rather than opinion or perception. This may be a simple editing fix and we have separately provided line-by-line comments to address this problem (see Attachment 4). If this is more than an editing problem and OIG asserts the stakeholders' unsubstantiated claims as facts, then OPP strongly objects to this Report since it provides no basis to support such conclusions.

Also, the Report often misstates how OPP considers residential exposures to pesticides. The Report accurately notes that OPP breaks down exposure estimates in the residential setting into estimates for four separate subgroups; however, parts of the Report state that OPP only has identified subgroups based on food consumption information. We believe it is extremely important that the OIG Report correctly describe OPP's consideration of subgroup exposure in the residential setting. Additional information on this topic is provided below.

We find the Report's discussion of the nine examples of OPP's consideration of subgroups to be confusing and misleading. OPP provided the OIG with several examples where subgroups were considered in risk assessment or regulatory actions. Some of these examples involved subgroups beyond those routinely considered. Others were examples of where consideration of children's subgroups caused EPA to take action to protect children. The OIG Report misleadingly combines all of these examples together without providing an adequate explanation of the reason for presenting the examples or even accurately describing the examples. The Report also inaccurately states that OPP lacked data on some of the subgroups. Finally, the discussion in Chapter 4 and Table 4.1 confusingly refer to "changes in tolerance levels" as if that is the only manner in which we protect subgroups.

**See OIG Comment in Appendix B, Note 10**

When OPP concludes a tolerance reassessment and finds a risk of concern, the most common risk mitigation strategy it would pursue would be termination of the pesticide's use or termination of specific uses. EPA does not ordinarily change the pesticide's tolerance level as a risk mitigation measure. For termination of a food crop use, the associated tolerance(s) would also be terminated. Often, the necessary risk mitigation is to revise or terminate other uses that are contributing to exposure, such as residential uses, to protect children. No tolerances are associated with such uses. Attachment 2 provides examples of mitigation measures taken in response to risks of concern identified during reregistration and/or tolerance reassessment. To the extent the OIG wants to present information pertaining to significant actions to protect children's subgroups that information, we have included that information in another attachment (see Attachment 3).

**See OIG Comment in Appendix B, Note 11**

Finally, there are a number of minor misstatements of fact and law for which we are separately providing suggested edits (please refer to Attachment 4). Additionally, for general reference we are including the following discussion of OPP's consideration of subgroups.

Subgroups Assessed by OPP

**As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures.** Those subgroups include several age-groupings of children, among other groups. These evaluations of subgroup risks have been deciding factors in every major risk reduction measure taken post-FQPA, with risks to children generally being the key factor. EPA also has embarked on several data-gathering exercises to determine if additional subgroups should be included in its routine analysis.

The types of subgroups of consumers assessed by OPP in its pesticide risk assessments can be broken into two main categories: (1) subgroups based on dietary consumption patterns; and (2) subgroups based on activity patterns in a residential setting.

For pesticides with food/feed-crop uses and dietary consumption, OPP evaluates pesticide risks for every pesticide in food for each of the following subgroups. These subgroups are based on extensive data on food consumption patterns:

**See OIG Comment in Appendix B, Note 12**

| By age group: | By season: | By ethnic status: | By region: |
|---|---|---|---|
| Infants <1, nursing<br>Infants <1 non-nursing<br>Infants<br>Children 1-2<br>Children 3-5<br>Children 6-12<br>Youths 13-19<br>Adults 20-49<br>Adults 50+<br>Females 13-49<br>Children 1-6<br>Children 7-12<br>Females 13+, pregnant, not nursing<br>Females 13+ nursing<br>Females 13-19, not pregnant, not nursing<br>Females 20+ not pregnant, not nursing<br>Females 13-50<br>Males 13-19<br>Males 20+ | Winter<br>Spring<br>Summer<br>Autumn | Hispanics<br>Non-hispanic whites<br>Non-hispanic black<br>Non-hispanic, non-white, non-black | Northeast<br>Midwest<br>Southern<br>Western |

OPP conducts exposure and risk assessments for each of these subgroups using models that have been extensively and scientifically peer-reviewed.

Further, although exposure to smaller, specialized subgroups is not routinely assessed by OPP, OPP is able and does perform such exposure assessments when conditions or circumstances warrant. Recent examples include analyses of triclopyr and lindane for exposures to certain Native Americans. In addition, OPP has contributed both financial resources and expertise toward the development of specialized dietary and aggregate exposure software for Native Americans (Tribal Lifeline™). In 2002, OPP initiated a contract to develop and modify the Lifeline software in such a way that expanded consideration could be given to Native

Americans living on reservations and practicing traditional Native American lifestyles (including diet). Specifically, this contract was initiated to better and more accurately represent exposure scenarios for two specific Native American communities, and to explore the options and approaches for complete representation of Native American communities. The software contract provides for consideration of the exposure scenarios of people living Native American lifestyles. Traditional diets based on hunted meats and gathered vegetables, seasonal changes of lodging, use of sweat lodges and other unique exposure scenarios are now part of the risk assessment model. As this model is developed, OPP intends to make more extensive use of it in instances for which we believe more generic models and approaches are not sufficient.

In addition to subgroups based on dietary patterns, OPP also uses several subgroups to assess differential risks from non-dietary exposure due to variation in behavior patterns. For each pesticide that has a registered residential use, OPP assesses the exposure and risk for the following subgroups, as appropriate for the use(s):

**See OIG Comment in Appendix B, Note 13**

- applicator (adult)
- post-application adult
- post-application youth
- post-application toddler

These subgroups take into account, for example, that a young child's post-application exposure to a pesticide may be substantially different than an adult's exposure, due to their different behavior, such as the tendency of young children to spend significant periods of time on the floor or lawn and to engage in hand-to-mouth activities.

Finally, OPP is continually evaluating and gathering data on whether risks to other subgroups should be specifically assessed. For example, several environmental and other organizations have argued that farm children face heightened pesticide exposures and have petitioned the Agency to assess farm children as a separate subgroup (i.e., the "Farm Children Petition"). OPP has comprehensively evaluated the available data on this question and determined that the available data do not support identifying farm children as a separate subgroup because their exposure to pesticides is not significantly different than non-farm children.

**See OIG Comment in Appendix B, Note 14**

Strategy for collecting and disseminating information about subgroups

**OPP agrees with this recommendation.** We are working with ORD's National Center for Environmental Assessment to have this information incorporated and distributed as part of EPA's Exposure Factors Handbook (next edition in 2007). OPP has also provided this information to exposure model developers.

Collaborative research efforts

With regards to the recommendation that OPP continue to work with ORD to develop a research agenda focusing on exposures to major identifiable subgroups, OPP acknowledges the

value of such collaboration. OPP has and will continue to work with ORD on science issues related to exposure to subgroups. OPP and ORD are well beyond the planning stage, as documented in Attachment 3. This attachment highlights OPP's and ORD's major collaborative efforts, past and present, to improve the human health risk assessment process under FIFRA and FFDCA. Many of these collaborations relate directly to scientific challenges posed by FQPA including the understanding and characterization of pesticide exposure to subgroups.

**IV.B. OIG Recommendation 4-2:**

**"Respond to petitions and requests from external stakeholders without further delay. Develop a policy that stresses the importance of Agency response to external comment in a timely manner."**

**OPP Response:**

We agree with the spirit of the recommendation that petitions should be responded to in a timely manner and we would admit that we have been frustrated that it has taken an extensive period of time to address some FQPA petitions. Very little in the implementation of a ground-breaking statute like the FQPA has been easy or quick. We object strongly, however, to the recommendation to respond to petitions "without further delay" if, for no other reason, than because EPA has either already responded to the petitions mentioned in the report or a court has upheld our response schedule as reasonable. We also object to the report's conclusions about "unreasonable delay;" as explained below, they have not been adequately supported. The unfortunate fact is that we believe that most of our disagreement with this section of the Report could have been resolved if only the OIG staff would have been willing to meet with us to discuss these concerns, or at least to discuss our comments on their draft Report. When we first learned of the OIG's conclusion regarding petition responses, we strongly objected to it noting that the OIG was drawing a broad conclusion based on a single petition (the 1998 Farm Children Petition) and without seeking OPP's explanation for the timing of its response. While the draft report is marginally better in how it deals with the Farm Children Petition, it compounds the original error by now raising other petitions which the OIG has not discussed with OPP. Because the OIG insists on pushing ahead without stopping to learn the facts or discuss the flaws in their analysis, OPP reluctantly must commit to the written record the serious deficiencies in this section of the Report.

**See OIG Comment in Appendix B, Note 15**

Overview

OPP objects to the accuracy and fairness of this whole section of the Report. We perceive OIG as having two criticisms of OPP practice with regard to Administrative Procedures Act (APA) petitions. First, that OPP has not responded in a timely manner to such petitions and second, that OPP's responses have not been direct (i.e., OPP has not sent a letter directly to petitioners announcing its response). Although these may very well be valuable issues for the OIG to evaluate, this section is replete with serious flaws:

1. As mentioned, the main recommendation from this section – that OPP should respond to petitions without further delay – is unsupported by fact. Each of the petitions cited in the Report have either been responded to or a court has upheld the timing of OPP's response schedule.

**See OIG Comment in Appendix B, Note 16**

2. Although this section of the report purports to evaluate OPP's handling of FQPA petitions, it never discusses or considers OPP's approach to addressing such petitions.

**See OIG Comment in Appendix B, Note 17**

3. The Report's conclusion that OPP has unreasonably delayed responding to the 1998 Farm Children's Petition in violation of the APA is devoid of any legal reasoning. In fact, the legal analysis appears to have been prepared by individuals without legal training. Needless to say, the Report contains no defensible basis for its conclusion.

**See OIG Comment in Appendix B, Note 18**

4. The Report's description of OPP's response to the Farm Children Petition is rife with inaccuracies and mischaracterizations.

**See OIG Comment in Appendix B, Note 19**

Each of these points is discussed in turn below.

<u>The Referenced Petitions Have Been Responded To</u>

The OIG Report recommends that OPP respond to petitions and requests without further delay. We find this recommendation confusing, to say the least, given the status of the petitions discussed in the report. The only petition clearly identified in the Report is the 1998 Farm Children Petition filed by NRDC and a host of other organizations. EPA released a point-by-point response to this petition in May, 2004. 69 FR 30042, 30069-30070 (May 26, 2004). The Report also vaguely references petitions on the children's safety factor and on wood preservatives. EPA is aware of two petitions concerning the children's safety factor, one filed by NRDC and other environmental organizations and one filed by representatives from the pesticide and food industry. EPA responded to both of these petitions in the course of developing its 2002 policy statement on the children's safety factor and included a discussion of the issues raised by the petitions in the response to comment document for that policy. Finally, OPP has received a petition to cancel various wood preservatives. OPP has decided to respond to that petition in the course of making a FIFRA reregistration decision on these pesticides. In a case challenging the timing of EPA's schedule for response to this petition, a federal district court ruled in favor of OPP holding its approach was reasonable. <u>Beyond Pesticides v. Johnson</u>, 2005 Lexis 4895 (D.D.C. March 21, 2005) (finding a 4 year delay in responding to a petition to cancel was not unreasonable). Thus, the OIG's recommendation to respond to petitions "without further delay" has no basis.

**See OIG Comment in Appendix B, Note 20**

EPA's Approach to Addressing FQPA Petitions

Because the OIG Report does not discuss OPP's approach to addressing petitions, we have attempted to encapsulate it here. When allocating its resources, OPP's top FQPA priority is completing the 10 year tolerance reassessment program explicitly mandated by Congress in FQPA. With this goal as its top priority, OPP has often managed petitions by folding the response to them into more generalized actions in support of tolerance reassessment or other required actions that are part of the tolerance reassessment program. Thus, OPP has dealt with petitions concerning the children's safety factor and aggregate exposure in the context of the science policy papers and response to comment documents on those topics. Similarly, OPP responded to the Farm Children Petition as a part of the response to objections filed in a tolerance preceding that raised the same issues. (Earlier, OPP had provided preliminary responses to the petition both in is letter acknowledging receipt of the petition and in the response to comment document for OPP's children's safety factor policy document.). Such an approach has led to a lapse of time between the filing of a petition and the OPP response. Before concluding that any particular length of time is unreasonable, however, OPP believes it is necessary for the OIG to consider both OPP's need to combine issues for efficiency purposes in meeting its tolerance reassessment deadlines and the complexities of the issues presented by the petition. For petitions that call on OPP to make broad policy pronouncements, it makes little sense when OPP is already in the process of formulating policy on issues related to the petition to abort its policy-making process to first respond to a petition. FQPA policy development, not unlike rulemaking, tends to be a fairly arduous process in which both public and intra- and inter-agency comment as well as peer review is sought and considered. When OPP receives a petition, it incorporates the issues raised as part of its on-going regulatory work, as appropriate, and in accordance with its on-going priorities. Similarly, for petitions that raise complex factual and scientific issues, the reasonableness of the time in responding depends on an analysis of the complexity of the issues presented.

**See OIG Comment in Appendix B, Note 21**

Because the OIG does not even take into account OPP's approach to addressing petitions, its evaluation of OPP's performance with regard to responding to petitions has little value.

**See OIG Comment in Appendix B, Note 22**

The OIG's Legal Conclusion on Unreasonable Delay is Without Support

The OIG's conclusion that EPA unreasonably delayed its response to the Farm Children's Petition in violation of the Administrative Procedures Act (APA) is unfounded. The OIG's analysis fails to identify the appropriate legal test for unreasonable delay, ignores almost all relevant facts, and misses the most relevant legal precedent.

**See OIG Comment in Appendix B, Note 23**

The OIG concluded that it was unreasonable for OPP to take six years to respond to the Farm Children petition and additionally, that it was unreasonable for OPP to spend one year to address extensive supplemental material submitted in support of the petition. Those conclusions were based on nothing more than the time involved in responding to the petition. In full

disregard of all legal precedent, the OIG did not consider the substantial competing demands on OPP's time – i.e., the mandatory tolerance reassessment deadline – or the complexity of the issues presented in the petition and the carefulness and detail of OPP's response. It is axiomatic, however, that an evaluation of the reasonableness of the timing of an agency action requires a fact-driven inquiry. Oil, Chem., & Atomic Workers v. OSHA, 145 F.3d 120, 123 (3rd Cir. 1998) (resolution of unreasonable delay claim in "a particular case is fact-intensive."). Indeed, unreasonable delay cases uniformly follow a well-established multi-factor test in assessing the reasonableness of the timing of the agency's action. See, e.g., In re: International Chemical Workers Union, 958 F.2d 1144, 1149-1150 (D.C. Cir. 1992) (describing a four factor test); Qwest Communications Int'l, Inc. v. FCC, 398 F.3d 1222, 1238 (10th Cir. 2005) (adding a fifth factor: "consideration of the complexity of the task envisioned by a court's remand order").

Instead of investigating the relevant facts surrounding the Farm Children's Petition, the OIG relies only upon broad statements from a single judicial decision without analyzing the either the facts of that decision or the court's multi-factor test for making unreasonable delay determinations. See In re: American Rivers and Idaho Rivers United, 372 F.3d 413 (D.C. Cir. 2004). Even a cursory analysis of the American Rivers decision would have shown a significant factual difference between that case and the present situation in that the agency there defended primarily by arguing it was not obligated to respond to the petition at issue. Id. at 418, 420 ("FERC offers no "plea of administrative error, administrative convenience, practical difficulty in carrying out a legislative mandate, or need to prioritize in the face of limited resources.""). Equally damaging to the OIG's legal conclusion is its failure to consider much more relevant precedent. Just recently, a federal district court upheld a lengthy OPP delay in responding to a petition, based on a similar justification to OPP's reason for delaying its response to various FQPA petitions. See Beyond Pesticides v. Johnson, 2005 Lexis 4895 (D.D.C. March 21, 2005). In that case, a four year delay in responding to a petition to cancel was not considered "unreasonable" because EPA was coordinating response to the petition with FIFRA reregistration. Ironically, the OIG scolds EPA for not responding to this very petition.

**See OIG Comment in Appendix B, Note 24**

These flaws render the OIG's legal analysis completely meritless.

**See OIG Comment in Appendix B, Note 25**

Factual Inaccuracies and Mischaracterizations

The Report contains numerous inaccurate statements and mischaracterizations concerning OPP's response to the Farm Children Petition. First, in the second paragraph in this section, the OIG states: "The agency addressed *many* aspects of the 1998 NRDC petition in the Federal Register order . . . ." By using the term "many", the OIG report implies that some or even a majority of the issues in the petition were not addressed. In fact, in responding to the petition, OPP individually examined each of its six requests and responded to each one of them. OPP also exhaustively discussed the data relied upon by the Petition. Any implication by the OIG that EPA did not fully address the 1998 NRDC petition is wholly without a factual basis.

Second, this same paragraph also notes that "NRDC was not immediately mailed a copy of the ruling . . . ." Although that is true, the statement is very misleading in that it creates an

impression that NRDC was not aware of the document containing OPP' petition response. NRDC certainly had actual notice that the document had been published since EPA's General Counsel's office had discussions with NRDC concerning the Order immediately following its entry. Moreover, we think it is important to mention that the main issue discussed in this Order was the exposure of farm children to pesticides. It is not as if OPP placed its petition response in some random document that NRDC was not likely to see.

Third, this paragraph further states "NRDC received word that the Imidacloprid decision served as a response to the petition on August 23, 2005, one year after the publication of the decision in the Federal Register." This is inaccurate on several levels. Any reasonable person would recognize as a "response" a document the provided a detailed response and analysis of each of the six demands in the Farm Children Petition and explicitly stated "[a]lthough EPA prior *to this action* has not issued a formal response [to the Petition]. . . ." 69 FR 30042, 30046 (May 26, 2004) (emphasis added). Moreover, in the context of litigation with NRDC on a similar issue, EPA filed papers in court in the Spring of 2005 noting that it had responded to the Farm Children Petition.

**See OIG Comment in Appendix B, Note 26**

The "Directness" of OPP's Response to Petitions

Finally, as noted above, the OIG is critical of OPP for not directly mailing petition responses to petitioners. Again, however, the OIG fails to discuss or consider OPP's approach to publishing its petition responses. OPP's approach has been to include its response to petitions in broadly-distributed public documents that have been available on OPP's website or in the Federal Register. OPP has not attempted to hide its responses. On the contrary, it has included them in documents likely to get the broadest public distribution. If the OIG believes that OPP should take additional steps and send a letter directly to the petitioners, OPP will consider such steps to further transparency.

**See OIG Comment in Appendix B, Note 27**

**Appendix B**

# *OIG Comments on Agency's Response*

1. With the enactment of FQPA, the need for extensive broad public involvement was clear. OPP acknowledges in its response that, at a minimum, public participation should include at least one pre-signature public comment period for all pesticides except those presenting the lowest risks. According to OPP's public participation process, formal public comment periods are the primary method by which OPP allows for public participation. Allowing for public comment *after* a decision is made does not allow for the same type of stakeholder confidence as soliciting pre-signature public participation. Additionally, allowing formal public comment periods prior to the release of a final decision document may preclude the Agency from having to amend decisions once they are made. We believe that proactively requesting public comment encourages stakeholder confidence in Agency decisions. Without OPP actively seeking pre-signature public comment, the public may continue to raise concerns regarding the transparency of the Agency decisions.

   According to the Agency's response, OPP believes that our reliance upon formal public comment periods does not accurately reflect all outreach involved in the decision-making process. Although there are other methods by which OPP can solicit some degree of participation, pre-signature public comment periods published in the Federal Register remain the most open and transparent method of involvement. While targeting specific stakeholders may add value to the decision making process, OPP can reduce the perception of bias by favoring formal public comment over informal outreach opportunities.

2. See Comment 1.

3. Table 3.3 clearly states that it comprises only final reregistration eligibility decisions. The 8 interim reregistration eligibility decisions highlighted by OPP are discussed in the first paragraph of that section: "Similarly, we reviewed one third (eight total) of the post-FQPA interim reregistration eligibility decisions and found that all of these decisions had formal comment periods prior to the issuance of the interim decision in accordance with the new policy." In no way does the table suggest that the Agency provided fewer opportunities for public participation during this time period for the interim reregistration eligibility decisions; it accurately reflects the number of public comment periods allowed for all final reregistration eligibility decisions signed during this time period.

4. Our sampling methodology included in the selection universe reregistration decisions made since the enactment of FQPA. Two of the five key principles of FQPA implementation focused on openness and public involvement. Evaluating public participation from FQPA's passage through the present should reflect OPP's dedication to these principles. OPP states that we do not accurately reflect current conditions because we evaluated public comment from FQPA's outset. FQPA was passed in 1996; however, according to OPP, it did not implement the draft public participation policy

until 2002. This policy was not finalized until 2004. The scope of our review was from the passage of FQPA to the present. To focus solely on the years covered by the draft and final policies, we would have ignored at least 6 years of decision-making by OPP. This omission would lead to an inaccurate picture of public participation in OPP since FQPA's passage. We acknowledge in various places in our report the progress EPA has made since 2002. We reviewed over one third of the universe of decisions made since FQPA. We reported on the positive results found in reviewing the interim reregistration eligibility decisions. In meetings with OPP staff, our sampling methodology was discussed and vetted by those involved in the reregistration process. We believe that our decision to examine public comment periods from FQPA passage in 1996 through the end of the field work process most accurately depicts OPP's work in implementing FQPA.

OPP expressed concerns that our sample does not accurately reflect its 2000 draft change in policy. OPP provided statistics related to the decisions made between 2002 and 2004. According to OPP, of the 26 reregistration eligibility decisions finalized during that period, 18 had two comment periods, 5 had one, and 3 had none. However, OPP's numbers, as provided within the Agency's response, are potentially confusing to the public. According to the Agency's Web site of the 26 reregistration eligibility decisions OPP discussed, 11 are interim reregistration eligibility decisions. This lack of distinction between interim reregistration eligibility decisions and reregistration eligibility decisions may be confusing to the public and thus reduce public confidence and the transparency of the process.

5. See Comment 1. Additionally, we are concerned that of all the stakeholder groups OPP mentioned as involved in public outreach activities prior to the reregistration eligibility decision signature but outside the realm of public comment, no public health or environmental advocacy groups are discussed. Targeting outreach at pesticide manufacturers and growers may miss out on a segment of the interested population. OPP stated that it has routinely consulted with major stakeholder groups prior to making its registration decisions. However, this would lead the public to believe that all stakeholder groups, including environmental and public health advocacy organizations, are consulted during OPP's decision-making process.

6. OPP states that it took the advice of a subcommittee formed to examine the potential for accidental exposure of young children to rodent control pesticides by issuing safety regulations in 1998. However, EPA revoked these protections in 2001. In August 2005, a Federal judge rejected the Agency's reversal, finding that its justification was without merit.

7. OPP objects to the section heading, "No Formal Public Comment Periods Found Prior to 2002." This heading, however, was removed prior to our providing OPP a revised draft report.

8. See Comment 1. We recognize that the Agency has a public involvement policy that allows public involvement to take many forms. As we reported, we agree that it is

important for OPP to have the flexibility to utilize various public participation processes (six-phase, four-phase, or one-phase). However, we believe that it is essential that OPP staff have clear criteria to use in assessing which phase is selected. In meeting with OPP staff, we were informed that the decision as to the level of public comment to employ is typically left to the discretion of OPP staff, and that it is usually a "judgment call." Additionally, such criteria would clearly articulate to the public and other interested stakeholders OPP's justification for deviation from the six-phase process, which allows the greatest opportunity for public comment.

9. While the Agency agreed with the recommendation to develop a strategy for collecting and disseminating information about subgroups, we believe it is imperative that the Agency first have a methodology in place describing at a minimum how it will identify additional subgroups on a case-by-case basis. We recommended that OPP document the methodology by which it currently considers additional subgroups who might potentially receive greater exposure than one of the standard subgroups. Additionally, providing this methodology to the public would increase transparency and public confidence in OPP's work.

10. We requested that OPP identify instances where pesticide tolerance setting decisions specifically incorporated the needs of subgroups, particularly in terms of non-dietary exposure pathways. Specifically we requested documents regarding: OPP's methodology for considering subpopulations, examples of instances in which subpopulation considerations changed the tolerance-setting process, and any changes in the non-dietary risk assessment process to take subpopulations into greater consideration. The information we received did not detail specific instances of OPP action to protect subpopulations from pesticide exposures; instead, we received reregistration eligibility decision and interim reregistration eligibility decision documents and policy decisions, the majority of which focused on dietary exposures and did not incorporate changes in the decision due to consideration of these subgroups. Based on our interviews with OPP staff, we assumed it was reasonable to consider the nine examples provided as the universe of decisions in which OPP addressed the question of major identifiable subgroups of consumers other than infants and children.

    OPP agreed with our recommendation to work with ORD to develop a research agenda focusing on exposures to major identifiable subgroups. We anticipate the goal of the research agenda would be to generate information on subgroups that OPP currently does not have. This research could be used to benefit future decision making.

    The statement that OPP is referring to as confusing is no longer in the report. In addition, the table heading was revised to more accurately reflect actions taken by OPP to protect subgroups.

11. See Comment 10. OPP objected to our examination of tolerance changes as a mechanism of reflecting impact and results from FQPA implementation. However, in meetings with high-level OPP staff, they recommended looking at individual registration eligibility decisions pre- and post-FQPA to ascertain the differences resulting from FQPA. We

were informed that there is rarely a chemical that goes through this process without some additional restriction on its use related to FQPA. Therefore, the reregistration eligibility decisions and tolerance reregistration eligibility decisions will evidence pre-FQPA and post-FQPA differences, especially the additional analyses related to safety factor decisions. We were told that looking at individual reregistration eligibility decisions and tolerance reregistration eligibility decisions "would be perfect" in illustrating the analytical and outcome differences related to FQPA. We will be addressing the impact of FQPA in an upcoming report.

12. We reported that OPP traditionally used a dietary exposure model that examines at least 27 different subgroups, which is consistent with the table provided in the Agency's response. Moreover, during our field work, we specifically asked for the methodology OPP uses in identifying and assessing subgroups in regard to non-dietary exposure. As we reported, in evaluating residential exposures, OPP evaluates four additional subgroups, including toddlers, youth, young adults, and applicators. While we did not evaluate individual decisions or the methodology used by OPP in conducting assessments, we recognized that there is still controversy as to whether additional subgroups should be examined. Additionally, in some instances, additional data will be needed to determine the susceptibility of such subgroups. We agree with OPP that the identification of subgroups is complicated and requires additional information and research. We will examine the extent to which OPP has "extensive data on food consumption patterns" in the forthcoming report on opportunities to improve data quality.

13. According to a 2000 GAO report, "As part of its implementation of the Food Quality Protection Act, EPA is revising the way it assesses residential pesticide exposures to better account for farm children's exposures. Among other things, in setting tolerances, EPA will consider pesticides that are tracked into homes and pesticide exposures children receive through spray drift in agricultural areas. As of November 1999, EPA had not completed its revision of methods to assess residential pesticide exposures." However, OPP standard procedures do not necessarily address take-home and spray drift exposures in assessing the potential for residential, non-occupational exposures to children.

14. One of the goals of FQPA was to improve existing data on the potential pesticide exposure to infants and children, and on the outcomes of these exposures. OPP agreed with our recommendation to work with ORD to collect and disseminate information about subgroups. Where gaps exist, OPP needs to ensure that the research agenda addresses these gaps.

15. OPP stated that a number of issues it has with our report could have been alleviated if we were "willing to meet with [them] to discuss these concerns." However, we met with OPP staff after the draft report was issued to discuss concerns and later provided OPP a revised draft. Additionally, OIG staff had several phone conversations with OPP staff and legal counsel between OPP's receipt of the revised draft report and OPP providing Agency comments. Furthermore, we extended the customary draft comment period to twice its normal length to further accommodate OPP. The meetings and conversations

discussed above were in addition to numerous discussions with OPP staff at various levels throughout our evaluation.

16. OPP strongly objected to the recommendation that OPP should respond to petitions "without further delay." However, that wording was removed prior to our providing OPP a revised draft report.

17. The focus of our evaluation was on the responsiveness of OPP to stakeholder petitions and requests. We did not focus on OPP's approach to addressing petitions; rather, we focused on one consequence of OPP's approach, which we concluded is contrary to the Agency's policy of openness and transparency.

18. See Comment 16. The Agency stated that conclusions drawn by the OIG were "devoid of any legal reasoning." However, this language was revised prior to our providing OPP with a revised draft report. We conducted a policy – not a legal – analysis of the Agency's responsiveness. In conducting our policy analysis, we determined that the responses by OPP to the petitions in question were inconsistent with the intent of Agency policy regarding transparency. While "OPP's approach has been to include its response to petitions in broadly-distributed public documents that have been available on OPP's website or in the Federal Register," we believe that OPP should take additional steps and specifically identify each such policy iteration as a response to a specific petition. OPP should mail a copy of these responses directly to the petitioners as a means to increase clarity and public confidence.

19. OPP states that our description of OPP's response to the Farm Children Petition is "rife with inaccuracies and mischaracterizations." This section was modified and edited significantly to address what OPP viewed as inaccuracies and mischaracterizations. At this time, we believe we have reported the condition accurately.

20. See Comment 16.

21. See Comment 18.

22. See previous discussions in Comments 19-22.

23. We did not in any version of our report conclude that OPP's lack of responsiveness "violated" APA. We did not conclude in the draft report that OPP had an unreasonable delay. Also, we only conducted a policy review and analysis of these issues; we did not conduct a formal legal analysis. See previous discussions in Comments 16-19.

24. See Comments 16-23. Additionally, in numerous interviews, we heard a variety of opinions on the validity and finality of the imidacloprid order as a response to the Farm Children Petition. The overall perception among the petitioners was that the imidacloprid decision does not resolve the petition. Moreover, OPP has never commented on the impact of the delay on current and future pesticide decisions. Our focus within the report was on the perception of OPP's unresponsiveness.

25. Again, the OIG did not conduct a legal analysis, but rather a policy analysis on the impact of OPP's practices on public confidence and perceptions. See previous discussions in Comments 16-24.

26. See comments 18-24.

27. OPP believes that we imply its responses to petitions have been hidden. The OIG evaluation was not a review of OPP's approach in responding to petitions but rather its responsiveness and the impact of the approach taken by OPP. According to the Agency's response, OPP has included responses to petitions in broad public distributions, such as policy documents or individual pesticide decision. However, this approach is not clear and transparent to petitioners and the public as to when and how the petitioners' concerns were addressed. For example, we found various opinions regarding the status of the petition during the course of this evaluation. It was unclear as to whether the Agency had responded to the petition. Apparently recognizing that, OPP issued a letter on August 23, 2005, to the petitioners informing them that the Imidacloprid order was in response to their petition. In the Agency's response, OPP agreed to consider taking additional steps in responding to petitions to further transparency.

**Appendix C**

# *FQPA Major Science Papers Receiving Public Comment Periods*

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|---|
| Draft Toxicology Data Requirements for Assessing Risks of Pesticide Exposure to Children's Health |
| Draft Exposure Data Requirements for Assessing Risks of Pesticide Exposure to Children |
| Standard Operating Procedures (SOPs) for Residential Exposure Assessment |
| Guidance for the Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs |
| Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment |
| Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern |
| The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorous and Carbamate Pesticides |
| The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management |
| Consideration of the FQPA Safety Factor and Other Uncertainty Factors in Cumulative Risk Assessment of Chemicals Sharing a Common Mechanism of Toxicity |
| Drinking Water Screening Level Assessment, Part A: Guidance for Use of the Index Reservoir in Drinking Water Exposure Assessments |
| Standard Operating Procedure for Incorporating Screening-Level Estimates of Drinking Water Exposure in Aggregate Risk Assessments |

**Appendix D**

# *Results on Public Participation for Sampled Final Reregistration Eligibility Decisions*

## Universe: All OPP Final Reregistration Eligibility Decisions, October 1996-February 2005

| Chemical | Date of Final Decision (Month/Year) | Was Formal Public Participation Solicited Prior to Issuance of Final Decision? |
|---|---|---|
| **Aluminum phosphide** | 9/1998 | NO |
| **Chlorophacinone** | 7/2004 | NO |
| **Chlorothalonil** | 9/1998 | NO |
| **Cycloate** | 9/2004 | YES |
| **Deet** | 4/1998 | NO |
| **Dichlobenil** | 9/1997 | NO |
| **Diclofop-methyl** | 9/2000 | NO * |
| **Diphacinone and salts** | 9/1997 | NO |
| **Diuron** | 9/2003 | YES |
| **Folpet** | 9/1999 | NO |
| **MCPA** | 9/2004 | YES |
| **Oxyfluorfen** | 10/2002 | YES |
| **Pebulate** | 9/1999 | NO |
| **Pendimethalin** | 4/1997 | NO |
| **Terbacil** | 9/1997 | NO |
| **Terrazole** | 9/2000 | NO * |
| **TFM** | 9/1999 | NO |
| **Thiobencarb** | 9/1997 | NO |
| **Thiodicarb** | 9/1998 | NO |
| **Triclopyr Salts and Esters** | 9/1997 | NO |
| **Troysan** | 12/1996 | NO |

* Risk assessment was made available via a Federal Register notice but, according to the notice, no formal comment period was granted.

**Appendix E**

# *Distribution*

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