U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Evaluation Report

EPA Needs to Comply with the Federal Insecticide, Fungicide, and Rodenticide Act and Improve Its Oversight of Exported Never-Registered Pesticides

Report No. 10-P-0026

November 10, 2009

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Abbreviations

EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FPAS	Foreign Purchaser Acknowledgement Statement
FQPA	Food Quality Protection Act
FY	Fiscal Year
GAO	Government Accountability Office
OIG	Office of Inspector General
OPP	Office of Pesticide Programs
USDA	U.S. Department of Agriculture

Cover photo: Ripe tomato on vine. (EPA OIG photo)

U.S. Environmental Protection Agency
Office of Inspector General

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At a Glance

Catalyst for Improving the Environment

Why We Did This Review

We initiated this review to evaluate whether the U.S. Environmental Protection Agency (EPA) has properly implemented Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 17(a) with respect to the Foreign Purchaser Acknowledgement Statements (FPASs), and whether controls are in place to ensure the safety of imported foods.

Background

Pesticides not registered for use in the United States may be manufactured domestically and exported abroad. FIFRA Section 17(a) requires that before an unregistered pesticide is exported, the foreign purchaser must sign an FPAS acknowledging awareness that the pesticide is not registered and cannot be sold for use in the United States.

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

To view the full report, click on the following link:
www.epa.gov/oig/reports/2010/20091110-10-P-0026.pdf

EPA Needs to Comply with the Federal Insecticide, Fungicide, and Rodenticide Act and Improve Its Oversight of Exported Never-Registered Pesticides

What We Found

EPA is not complying with FIFRA Section 17(a) which is, in part, intended to notify the government of an importing country that a potentially hazardous pesticide was imported into that country. Specifically, EPA does not comply with requirements to provide notice to all countries importing unregistered pesticides. EPA does not ensure manufacturer compliance with FIFRA Section 17(a) notification requirements. Consequently, there is no assurance EPA is receiving the entire universe of export notifications in any given year. Finally, export data on unregistered pesticides are insufficient for tracking and analysis.

Export notification practices and data requirements are insufficient to monitor for the potential re-entry of never-registered pesticides on imported foods or to determine whether a dietary risk to U.S. consumers exists. The safety of unregistered pesticides intended solely for export is not evaluated by EPA. Therefore, the risk associated with never-registered pesticides is unknown. EPA does not know the pesticide class, volume, use, or final destination of unregistered U.S. pesticide exports. EPA also cannot provide the Food and Drug Administration and the U.S. Department of Agriculture with information needed to monitor and detect pesticide residues from pesticides that have never been registered for use in the United States. Therefore, the extent of dietary risk from never-registered pesticide residues on imported foods is unknown.

What We Recommend

We recommend that EPA comply with statutory mandates, implement management controls, and establish procedures for identifying and mitigating any dietary risk to consumers from never-registered pesticides.

The Agency stated that it had now checked the specific subset of FPASs highlighted in the report. The Agency concluded that since it did not find a problem after reviewing these Fiscal Year 2007 FPASs, there is no basis for change in procedures or further analysis. The Agency comments were nonresponsive to the findings and recommendations. The Agency addressed neither its compliance with FIFRA Section 17(a) requirements nor the insufficient control process to monitor for potential re-entry of never-registered pesticides. All recommendations are undecided.

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

OFFICE OF
INSPECTOR GENERAL

November 10, 2009

MEMORANDUM

SUBJECT: EPA Needs to Comply with the Federal Insecticide, Fungicide, and Rodenticide Act and Improve Its Oversight of Exported Never-Registered Pesticides
Report No. 10-P-0026

FROM: Wade T. Najjum
Assistant Inspector General for Program Evaluation

TO: Stephen A. Owens
Assistant Administrator for Prevention, Pesticides and Toxic Substances

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

The estimated cost of this report – calculated by multiplying the project's staff days by the applicable daily full cost billing rates in effect at the time – is $736,223.

Action Required

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

If you or your staff have any questions regarding this report, please contact me at (202) 566-0827; or Jeffrey Harris, Director of Cross-Media Issues, at (202) 566-0831 or harris.jeffrey@epa.gov.

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Chapter 1
Introduction

Purpose

The overall objective of this evaluation was to determine how well the current systems of the U.S. Environmental Protection Agency (EPA) assist in preventing the entry of unregistered pesticide residues on imported food.[1] Specifically, we sought to evaluate:

- Has EPA properly implemented the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 17(a) with respect to the Foreign Purchaser Acknowledgement Statement (FPAS) requirement?
- Are controls in place to ensure that the imported food supply is not vulnerable to unregistered pesticides?

Background

On September 30, 1978, Congress amended FIFRA to include export notification provisions for pesticides intended solely for export. Pesticides not registered for use in the United States may still be manufactured domestically and exported abroad, as long as the exporters comply with labeling and notification requirements defined under FIFRA Section 17(a). FIFRA Section 17(a) requires that before an unregistered pesticide is exported from the United States, the foreign purchaser must sign a statement acknowledging an awareness that the pesticide is not registered and cannot be sold for use in the United States. The pesticide exporter is then required to transmit an FPAS for the pesticide product to EPA certifying that the FPAS preceded the initial shipment. FIFRA Section 17(a) requires EPA to forward copies of all FPASs received to the appropriate government officials of the importing countries.

EPA's Pesticide Registration Process

EPA must evaluate any pesticides before they can be marketed and used in the United States to ensure that they will meet federal safety standards. EPA must also ensure that pesticides registered for use in the United States will not have unreasonable adverse effects on humans and the environment. As part of the registration process, EPA examines:

[1] EPA defines a pesticide as any substance intended to destroy, prevent, or repel pests such as insects, weeds, fungi, and rodents. This term applies to insecticides, herbicides, fungicides, and various other substances used to control pests.

- the active and inert 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 registers pesticide products and their uses on specific pests and under specific circumstances. For example, EPA may determine that "Pesticide A," registered for use on apples, may not be used legally on grapes. The safety of unregistered pesticides intended solely for export is not evaluated by EPA.

Before allowing the use of a registered pesticide on a food crop, EPA sets a tolerance for that food-pesticide combination. A tolerance is the amount of pesticide residue allowed to remain in or on a food commodity.[2] Tolerances apply to both imported and domestic commodities. Import tolerances may be established for pesticides that are not registered for use in the United States but are commonly used on foreign commodities. Import tolerances allow pesticide residues for pesticides otherwise unregistered for use in the United States to be on imported foods destined for domestic consumption. Food commodities with pesticide residues that exceed tolerance levels or have residues that are not registered for use on that specific commodity are subject to enforcement actions by the Food and Drug Administration (FDA).

Federal Pesticide Monitoring

Three federal agencies share responsibility for preventing unsafe levels of pesticide residues in the Nation's food supply. EPA determines the safety of new pesticides, sets tolerance levels for pesticide residues on foods, and administers FIFRA requirements for exporting unregistered pesticides. Except for meat, poultry, and certain egg products, for which the U.S. Department of Agriculture (USDA) is responsible, FDA enforces tolerances for both imported and domestic foods shipped in interstate commerce. FDA's Pesticide Residue Monitoring Program enforces EPA tolerances through selective regulatory pesticide residue monitoring.

FDA enforces EPA-established tolerances through focused regulatory monitoring of pesticide residues on food commodities. According to FDA, the goal of FDA's monitoring program is to carry out selective monitoring to achieve an adequate level of consumer protection. If residues are found at a level above an EPA tolerance, or measurable levels of residues are found on imported foods for which EPA has no established tolerance, shipments are refused entry into U.S. commerce.

[2] Tolerances may be established for products or separate active ingredients within a product.

A 2008 report from USDA reviewed FDA's Import Retrieval Refusal system results from 1998-2004.[3] USDA reported that vegetables and vegetable products had the largest total number of violations. The most frequently cited violation was unsafe residue levels. These violations include pesticide residues not registered in the United States and residues that exceeded tolerance levels set by EPA. In 2002 and 2003, more violations occurred on imported produce for unregistered pesticide residues than for residues that exceeded U.S. tolerance levels.

Noteworthy Achievements

Under FIFRA, EPA is required to cooperate and participate in international efforts on pesticide research and regulations. We found that the Office of Pesticide Programs (OPP) is engaging in ongoing international efforts contributing to developing improved pesticide research and regulations, including:

- **Work Sharing and Information Exchange:** Collaboration with other governments and stakeholders for reviews of new pesticide registrations or re-assessments.
- **Harmonization of Regulations and Tolerances:** Activities to facilitate harmonized regulations and tolerances improving the efficiency of pesticide evaluation, risk assessment, and managing and regulating new and existing pesticides.

Scope and Methodology

We conducted this performance evaluation in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the evaluation to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based upon our objectives. We performed our evaluation from October 2008 through August 2009.

Our review included examining applicable laws, regulations, and Agency guidance. We also reviewed internal controls relevant to our objectives. We reviewed the universe of FPASs received for 2007. We met with Agency staff and with officials from both the USDA and the FDA, along with other interested stakeholders.

Appendix A provides further details on our scope and methodology.

[3] Jean C. Buzby, Laurian J. Unnevehr, and Donna Roberts. *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Report.*, EIB-39. U.S. Department of Agriculture, Economic Research Service, September 2008.

Chapter 2
EPA Is Not Complying with FIFRA Section 17(a) Requirements

EPA is not complying with FIFRA 17(a), which is, in part, intended to notify the government of an importing country that a potentially hazardous pesticide has been exported and is not registered and cannot be sold for use in the United States. EPA does not determine manufacturer compliance with FIFRA Section 17(a) notification requirements. Consequently, EPA may not be receiving the entire universe of export notifications in any given year. EPA has decided not to comply with statutory requirements to provide notice to all countries importing unregistered pesticides. Export data on unregistered pesticides are insufficient for tracking and analysis.

Regulation on Exporting Unregistered Pesticides

As discussed in Chapter 1, FIFRA Section 17 addresses exporting unregistered pesticides from the United States. FIFRA requires prior notification from the manufacturer or exporter to the importer of these pesticides' unregistered status. The pesticide exporter or manufacturer is then required to transmit the FPAS to EPA and certify to EPA that the shipment did not occur prior to EPA receiving the FPAS.

FIFRA Section 17(a) requires that EPA forward copies of all FPASs received to the appropriate government officials of the importing countries. The intent of this section is to notify the government of the importing country that a pesticide judged hazardous to human health or the environment, or for which no such hazard assessment has been made, was imported into that country. Appendix B outlines a logic model that describes these processes and additional controls EPA could use to ensure compliance with statutory mandates.

EPA Does Not Determine Manufacturer Compliance with Notification Requirements

We reviewed EPA's existing processes governing the receipt of FPASs. Based on our review, we found that EPA lacks reasonable assurance that it is receiving the universe of FPAS notices in a given year. EPA has a processing guide that documents receiving and safeguarding FPASs. However, no procedures are in place to determine if manufacturers are submitting all FPASs for unregistered pesticide exports as required. According to OPP staff, when OPP receives FPASs, it documents receipt and conducts no follow-up. OPP received 2,291

FPASs in 2007. Since OPP does not take any action to verify this information or ensure that the filings are comprehensive, this figure could be understated. OPP conducts no analysis on the FPASs received from manufacturers because it does not believe this exercise would hold sufficient value. EPA has an internal, automated system that tracks pesticide-producing establishments and the amount of pesticides manufacturers produce on an annual basis. FIFRA requires facilities that produce pesticides to register their establishments with EPA and to report annually the amount and types of pesticides produced and distributed, including the volume and type of all pesticides exported. While EPA could use the export production information contained in this system to determine whether OPP is receiving all necessary manufacturer data, we found OPP has chosen not to conduct any such reconciliation. If OPP conducted such an analysis, it would determine whether manufactures are complying with the FIFRA Section 17(a) requirement.

Lack of Compliance with FIFRA Section 17(a) Requirements for Forwarding FPASs

A copy of each FPAS received by EPA is required by statute to be transmitted to an appropriate official of the importing country. We found EPA does not forward most FPASs received. Rather than comply with the statutory mandate, OPP adopted a less rigorous practice. We reviewed the 2007 universe of 2,291 FPASs received. We found that only 55 of these FPASs, or less than 3 percent, were forwarded to foreign officials. All of the forwarded FPASs were for a particular pesticide: the granular formulations of carbofuran. OPP determined that only FPASs for these formulations of carbofuran should be forwarded to importing countries.

EPA proposed alternative criteria as substitutes to the FIFRA 17(a) statutory mandate in a 1995 white paper, publishing a Notice of Availability for public comment in the Federal Register.[4] According to this white paper, FIFRA Section 17(a)'s requirements resulted in too many export notices that "trivialized the effect of its export notification system" and cited that the current mandate may be of little or no concern to other governments. Despite its concerns with the inefficiencies created by compliance with the statute, we found that OPP has not directly sought to have Congress amend or modify FIFRA Section 17(a). While OPP proposed draft modifications to EPA's pesticide export notification policies, the current practice for forwarding FPASs has never been formalized as an Agency policy or criterion.

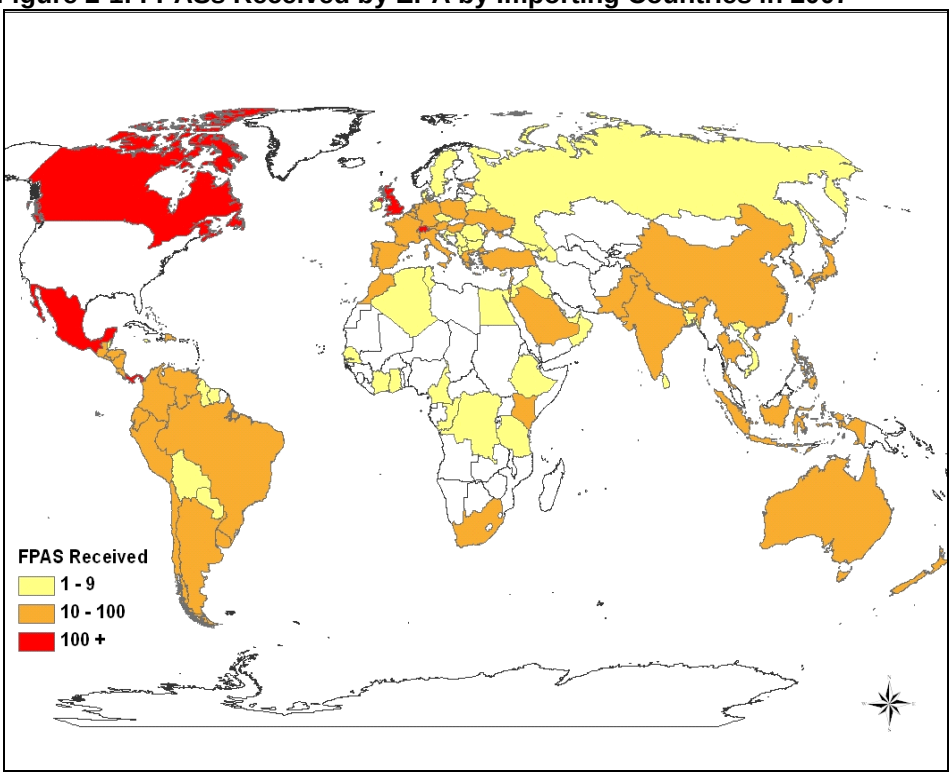
In reviewing the FPASs for 2007, we found that EPA did not forward 2,236 FPASs. Consequently, foreign governments are not receiving all information as

[4] "Reinventing EPA's Pesticide Export Notification Program," September 20, 1995. The intent of this document was to improve the system for notifying foreign governments of unregistered pesticide exports from the United States. This document was designed as a preliminary proposal to reinvent FPAS procedures. It remains in draft form.

required under FIFRA 17(a), leaving them potentially unaware of any hazards associated with pesticides imported into their countries. EPA did not forward between 1 and nearly 200 FPASs to the appropriate countries. For example, while EPA forwarded 4 FPAS notifications on exporting carbofuran to Mexico, EPA did not forward 97 other FPASs for 89 pesticide products that were exported to Mexico in 2007. Although EPA received 79 and 198 FPASs that identified China and Canada as the respective destinations, EPA did not forward any of these notifications.

Figure 2-1 illustrates the relative numbers of FPASs that EPA received and should have forwarded to the importing countries. We noted that two of the top six importing countries in 2007 where FPASs were not forwarded—Canada and Mexico—are also two of the top three sources of U.S. food imports (measured by value) in 2007.[5]

Figure 2-1: FPASs Received by EPA by Importing Countries in 2007[6]



Source: OIG analysis of 2007 FPASs received.

EPA Has Insufficient Data on U.S. Exports of Unregistered Pesticides

EPA lacks sufficient data on U.S. exports of unregistered pesticide products for tracking and analysis. FPASs are required to include the following information:

[5] See Appendix C for an illustration of the top sources of U.S. food imports in 2007.
[6] See Appendix D for specific details regarding receipt and forwarding of the 2007 FPASs.

- Name, address, and EPA identification number of the exporter;
- Name and address of the foreign purchaser;
- Identity of the product and the active ingredient(s);
- The country or countries of final destination[7] (if known) for the export shipment;
- A statement that indicates that the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States;
- The signature of the foreign purchaser; and
- The date of the foreign purchaser's signature.

However, FPASs do not provide the following:

- Quantity or volume,
- Foreign commodity usage,
- Safety procedures,
- Pesticide class, or
- Analytical methods and reference standards for residue detection that would be required for regulatory monitoring.

FPASs are submitted on an annual or first shipment basis. EPA has no means to determine the amount of unregistered and never-registered pesticides being exported. Pesticides have a variety of potential uses, one of which is to prevent or eliminate pests on food crops. However, U.S. exporters do not declare on FPASs the intended use of the pesticide product in the importing countries. Therefore, EPA lacks the ability to identify food-use pesticides and their usage on foreign commodities that may be imported to the United States.[8] If FPASs contained additional information, EPA could more accurately track and monitor where the pesticides are ultimately going, what commodities they are being used for or on, and the quantities of unregistered and never-registered pesticides exported.

In EPA's 1995 white paper, the Agency documented the consideration of the development of a standardized form to both "ease EPA's data entry and tracking burden," and "improve recipient countries ability to process the information" provided on the FPAS. Furthermore, the document discussed expanding the information provided on FPASs to include additional information such as:

- Health and safety data;
- Tolerance status, if applicable;
- Hazard classification; and
- Available use information.

[7] According to OPP, the destination listed on FPASs does not mean that the pesticide product will remain in that country because it is possible that the pesticide may be further shipped to other destinations.
[8] See Appendix E for an analysis of EPA's risk reduction activities for registered food-use pesticides.

However, EPA has not taken necessary steps to collect additional information or seek amendment of FPAS data requirements.

Conclusion

EPA does not have procedures in place to determine manufacturer compliance with FIFRA Section 17(a) notification requirements. Consequently, there is no assurance EPA is receiving the entire universe of export notifications in any given year. Furthermore, we found that EPA does not comply with FIFRA Section 17(a) requirements to forward FPASs to all foreign government officials. Therefore, the importing countries are not being notified of pesticides not registered for use in the United States entering their country. Additionally, EPA obtains limited data on U.S. exports of unregistered pesticide products, which hinders its ability to track and monitor the export of unregistered pesticides.

Recommendations

We recommend that the Acting Assistant Administrator of the Office of Prevention, Pesticides and Toxic Substances:

2-1 Comply with FIFRA Section 17(a) forwarding requirement or seek official relief.

2-2 Develop and implement management controls to ensure EPA is receiving FPASs from all manufacturers as required by FIFRA Section 17(a).

2-3 Develop procedures for reporting FPAS information, including intended use information.

Agency Comments and OIG Evaluation

The Agency was nonresponsive to the findings and recommendations in this chapter. The Agency did not address its noncompliance with FIFRA Section 17(a) requirements, or the insufficient management control process to monitor the export of unregistered pesticides. All recommendations are undecided. The Agency's complete written response is presented in Appendix F. The OIG's evaluation of Agency comments is presented in Appendix G.

Chapter 3
Extent of Risk from Never-Registered Pesticide Residues on U.S. Food Imports Is Unknown

EPA's current practices are insufficient to monitor for the potential re-entry of never-registered pesticides on imported foods or to determine whether a dietary risk to U.S. consumers exists. The safety of unregistered pesticides intended solely for export is not evaluated by EPA. Therefore, the risk associated with never-registered pesticides is unknown. As reported in Chapter 2, EPA does not know the pesticide class, volume, use, or final destination for all unregistered U.S. pesticide exports. EPA also cannot provide FDA and USDA with information needed to monitor and detect pesticide residues from never-registered pesticides. Therefore, the extent of dietary risk from never-registered pesticide residues on imported foods is unknown.

Never-Registered Pesticide Exports May Pose a Potential Risk on Imported Foods

Pesticide manufacturers must satisfy a series of EPA data requirements to register products for domestic use. However, manufacturers exporting unregistered pesticides are not required to provide EPA data regarding product hazard or risk. With the globalization of the world's food supply, some of the produce Americans consume comes from foreign sources.[9] A potential vulnerability exists that imported produce may contain residues of these unregistered pesticide exports. However, the degree of the vulnerability due to never-registered pesticide exports is unknown. OPP does not receive information such as where the pesticide will be used and on what commodity.

We analyzed the 2,291 FPASs received by the EPA in 2007 and found that nearly half (46 percent) were for pesticide products that were never registered for use in the United States. For never-registered pesticide products that consist of active ingredients contained in registered products but in different formulations, EPA may have some human health and environmental hazard data. However, the chemical content for some of these pesticides may be unknown because they have not been reviewed by EPA. Based on our review of EPA's FPAS files and available product data, we determined that 182 FPASs received by EPA were for pesticides with chemical components that were never registered for use in the United States.[10]

[9] See Appendix C for a map of import sources.

[10] The Agency conducted its own analysis of the 182 FPASs. According to the Agency, while most of these chemicals were not registered for use in the United States, they do not constitute an area of concern because the FPASs were for products that contained active ingredients that had either been registered by EPA in a different

As described in Chapter 2, manufacturers are not required to provide pesticide class, final destination,[11] foreign commodity usage, or health and environmental risks from never-registered pesticide exports from the data collected on the FPASs. These unknowns create gaps in the overall federal pesticide monitoring regime. Thirty years ago, the Government Accountability Office (GAO) reported on the need to monitor pesticide exports. Specifically, the report concluded:

> The uncontrolled export of hazardous pesticides poses dangers to U.S. citizens, as well as to people in other nations. The extent of danger, however, is not known, because the content, destination, and use of most exports are not monitored.[12]

Based on our review, the extent of risk still remains unknown due to the lack of information on pesticides that have never been registered for use in the United States. An analysis such as the one conducted for the 182 FPASs should be conducted for the remaining universe FPASs to fully determine where a risk exists.

Federal Monitoring Can Mitigate Risks from Registered and Cancelled Pesticide Residues

Over time, registered pesticide active ingredients, pesticide products, or certain uses of a registered pesticide have been cancelled. These cancellations occurred for various reasons, including:

- voluntary cancellation by the registrant,
- cancellation by EPA because required fees were not paid, or
- cancellation by EPA because an unacceptable risk could not be reduced by another action.[13]

Pesticides that have been cancelled for use cannot be used domestically or on imported foods. In addition, pesticides for which EPA has received no data regarding hazard or risk (never-registered pesticides) cannot be used in the United States but can be manufactured for export.[14] Table 3-1 defines the various registration statuses for pesticides.

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product formulation and/or had tolerances or specific exemptions from tolerance requirements for residues in food, pesticides still in the research and development stage, or products that were not pesticides. Two of the pesticide products, while not registered for use in the United States, have active ingredients that have tolerances and have been registered for use in the European Union. Our analysis of the Agency's response is in Appendix G.

[11] EPA requests that the final destination be provided, if known.

[12] Government Accountability Office. *Pesticides: Better Regulation of Pesticide Exports and Pesticide Residues in Imported Foods is Essential*. GAO/RCED-79-43, June 1979.

[13] For example, a large number agricultural, residential, and commercial uses of organophosphate pesticides were cancelled by EPA for this reason under the Food Quality Protection Act of 1996 (FQPA).

[14] U.S. pesticide manufacturers may choose not to seek EPA registration for many reasons, including cases where the pesticide is used on crops not grown or not commonly grown in the United States, the cost and resources needed

Table 3-1: Registration Status Definitions

Registration Status	Definition	
Registered	EPA has evaluated the pesticide to ensure that it will not have unreasonable adverse effects on humans, the environment, and nontarget species. For pesticides that may be used on food or feed crops, EPA also sets tolerances (maximum pesticide residue levels) for the amount of the pesticide that can legally remain in or on foods.	
Unregistered	**Cancelled**	**Never-registered**
	A pesticide product's registration has been removed due to any variety of reasons.	Never-registered pesticides have not completed EPA's registration process.[15]

Source: OIG evaluation of OPP documents.

EPA cancellations of pesticide products of high risk to infants and children have reduced their dietary risk. These EPA regulatory actions have been associated with the reduction in cancelled pesticide residues returning to the United States from abroad captured through USDA and FDA's monitoring programs. The effectiveness of the federal regulatory systems requires that EPA has sufficient product chemistry data to calculate risk and that FDA and USDA have data to detect and measure residues.

In 2006, OIG conducted an analysis of the dietary pesticide residue exposure data in the USDA's Pesticide Data Program. OIG evaluated the impact of the Food Quality Protection Act (FQPA) on dietary pesticide exposure risk for children.[16] We found that EPA's cancellation of the pesticides chlorpyrifos and methyl parathion under FQPA reduced 98 percent of the total pesticide dietary risk posed by high risk domestic commodities among infants and children in the United States.[17]

EPA actions on pesticide tolerances under FQPA reduced total pesticide dietary risk posed by cancelled pesticides on domestic foods. Primary imported food "risk drivers"[18] posing the highest dietary risk to infants and children included chlorpyrifos on apples, tomatoes, or sweet bell peppers, and methyl parathion present on processed green beans. Our review of chlorpyrifos and methyl parathion violations cited in FDA's Pesticide Residue Monitoring Program in

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to complete the registration process are onerous, or the lack of harmonization among different countries' registration processes is confusing or burdensome.

[15] For most never-registered pesticides, EPA lacks information regarding these products' potential hazard. However, never-registered pesticides may share a common active ingredient with other registered pesticide products. In this case, EPA would have some information regarding the parent chemical's toxicity.

[16] EPA–OIG. *Measuring the Impact of the Food Quality Protection Act: Challenges and Opportunities*. Report No. 2006-P-00028, August 1, 2006.

[17] Appendix E provides additional details on the case study.

[18] Risk drivers are the pesticide-food combinations of highest risk for consumers. Risk drivers account for the majority of dietary exposure risk from a given pesticide.

Fiscal Year (FY) 2006 found no violations for these high-risk, imported pesticide-food combinations. When there is sufficient pesticide product knowledge, EPA regulatory actions and the federal residue monitoring system work to capture and mitigate risks.

FDA and USDA Lack Necessary Information from EPA to Detect Never-Registered Pesticide Residues on Imported Foods

EPA lacks sufficient information to inform other federal agencies responsible for identifying pesticide residues on imported foods. Specifically, FDA would need information such as intended foreign use to determine which imported crops to test for pesticide residues. In the case of pesticides that have never been registered for use in the United States, FDA would need reference standards[19] and testing methodologies to determine the presence of these residues. For registered products under FIFRA, the manufacturer is required to provide EPA with pesticide residue chemistry data. Manufacturers are not required to submit data for unregistered pesticides under FIFRA, which prevents FDA from developing tests for these residues.

According to OPP, FDA is responsible for assuring imported foods are free of pesticide residues in excess of established tolerances, including those for which there are no tolerances. OPP stated that the absence of violations found by FDA on imported food validated that the system was working and no problem existed. However, FDA does not have the capabilities to detect pesticide residues from pesticides that have never been registered for use in the United States. FDA and USDA testing has detected unidentifiable residues on imported foods. These detections, called unknown analytical responses, may potentially be active ingredients from unregistered or never-registered pesticides. The frequency and occurrence of these unknown residues on imported foods is not currently tracked by these agencies. According to FDA, detection of these responses as never-registered pesticide residues would require information about the chemical content.[20]

EPA has not provided necessary guidance and information to FDA and USDA to conduct regulatory and dietary risk monitoring for never-registered pesticide residues. At a minimum, EPA would need to provide:

- Criteria for when the quantity and composition of a never-registered pesticide for export could pose an unreasonable dietary risk,
- The export destination countries and intended foreign pesticide use, and

[19] A reference standard is a pure pesticide sample used for calibrating test equipment for detecting pesticide residue.
[20] FDA Pesticide Residue Monitoring Program staff said they would require "firm intelligence" from EPA on the never-registered pesticides to be monitored. This intelligence would include the class of pesticide and reference standards for residue detection, foreign crop usage, and countries of origin for targeted sampling of imports. Additionally, FDA program staff stated that confirmation from EPA that never-registered pesticide residues pose a dietary risk would be necessary prior to regulatory monitoring for this specific subset of pesticides.

- Analytical testing methods and reference standards for residue identification.

Conclusion

The extent of danger posed by never-registered pesticides in the food supply remains unknown due to the lack of information on their export. Risks posed to the U.S. food supply from registered and cancelled pesticides are mitigated through EPA tolerance actions and FDA regulatory enforcement. EPA relies on FDA to assure that imported foods are free of pesticide residues in excess of established tolerances, including those for which there are no tolerances. However, EPA lacks sufficient information needed by other federal agencies to identify some exported unregistered pesticide residues on imported foods. FDA does not have the capabilities to detect pesticide residues from pesticides that have never been registered for use in the United States. Manufacturer export data submitted to EPA is insufficient to assess human health and environmental hazards posed to importing countries or dietary risk posed to the U.S. food supply. Limited export notification data fail to capture the quantity, foreign commodity usage, and residue detection standards necessary for EPA, FDA, and USDA to monitor U.S. never-registered pesticide exports and their potential re-entry on imported foods. Consequently, EPA does not know the extent of the associated risk.

Recommendations

We recommend that the Acting Assistant Administrator of the Office of Prevention, Pesticides and Toxic Substances:

3-1: Establish criteria to govern when the quantity and composition of a never-registered pesticide for export could pose an unreasonable dietary risk.

3-2 Establish procedures to mitigate risk from never-registered pesticides, including coordinating information with USDA and FDA.

Agency Comments and OIG Evaluation

The Agency was nonresponsive to the findings and recommendations in this chapter. The Agency questioned the analysis of the 182 FPASs determined to be never registered. The Agency conducted a subsequent analysis and concluded that while many of these chemicals were not registered for use in the United States, they did not constitute a concern because only two were for products that did not have a U.S. registration, tolerance, or exemption. The Agency's analysis illustrates our conclusion that the Agency control process does not provide assurance that FDA can detect potentially significant risks from unknown pesticides that EPA has not evaluated on imported foods. Our conclusion that the extent of dietary risk from never-registered pesticide residues on imported foods

is unknown is based on several factors: (1) EPA's current practices are insufficient to monitor for the potential re-entry of never-registered pesticides on imported foods or to determine whether a dietary risk to U.S. consumers exists; (2) the safety of unregistered pesticides intended solely for export is not evaluated by EPA; (3) EPA does not know the pesticide class, volume, use, or final destination of all unregistered U.S. pesticide exports; and, (4) EPA cannot provide FDA and USDA with information needed to monitor and detect pesticide residues from never-registered pesticides. See Appendix F for the Agency's complete written response. The OIG's evaluation of the Agency comments is presented in Appendix G.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Claimed Amount	Agreed To Amount
2-1	8	Comply with the FIFRA Section 17(a) forwarding requirement or seek official relief.	U	Assistant Administrator for Prevention, Pesticides and Toxic Substances			
2-2	8	Develop and implement management controls to ensure EPA is receiving FPASs from all manufacturers as required by FIFRA Section 17(a).	U	Assistant Administrator for Prevention, Pesticides and Toxic Substances			
2-3	8	Develop procedures for reporting FPAS information, including intended use information.	U	Assistant Administrator for Prevention, Pesticides and Toxic Substances			
3-1	13	Establish criteria to govern when the quantity and composition of a never-registered pesticide for export could pose an unreasonable dietary risk.	U	Assistant Administrator for Prevention, Pesticides and Toxic Substances			
3-2	13	Establish procedures to mitigate risk from never-registered pesticides, including coordinating information with USDA and FDA.	U	Assistant Administrator for Prevention, Pesticides and Toxic Substances			

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

Appendix A

Detailed Scope and Methodology

We conducted this evaluation from October 2008 through August 2009. To address our overall objective, we met with Office of Pesticides Programs (OPP) program staff at headquarters, and reviewed FIFRA Section 17 policies and procedures currently in place. We reviewed the legislative history for FIFRA Section 17(a), as well as proposed changes and amendments to this legislation over time, including the Rotterdam Convention. Interviews with staff of an external environmental and public health organization and other advocates helped to identify pesticide residue concerns from a public perspective. We also met with an industry advocacy group to ascertain its opinions on FIFRA Section 17 requirements. We also reviewed past GAO reports and publicly available reports and Websites.

To determine whether controls were in place to ensure the safety of imported foods from unregistered pesticide residues, we reviewed FDA food-related import refusals and FDA regulatory monitoring violations data for cancelled pesticide residues. We interviewed FDA program staff and a USDA program official to determine the role of these federal agencies in monitoring pesticide residues on U.S. food commodities and FDA and USDA's policies and practices regarding monitoring unregistered pesticides.

To identify the universe of FPASs received, we obtained the FPASs held in hardcopy by OPP from 2007. We reviewed the hardcopy files as well as an electronic database file of 2007 FPAS information. We eliminated any duplicate data. With these documents, we created a searchable database of all FY 2007 FPASs to analyze trends, registration statuses, and destinations. We also used these data to determine the number of FPASs not transmitted to foreign government officials as required under EPA's current procedures and as required by FIFRA.

We used Microsoft Excel for all figures and maps. We created maps using the ArcMap component of ArcGIS.

Prior Reports

The OIG has not published work on exporting unregistered pesticides; international notifications of restricted, banned, or suspended pesticides; or EPA's international efforts on pesticide research and regulations. However, the OIG has conducted previous work in pesticide regulation, the most recent of which is a series of three reports on EPA's implementation of FQPA. A 2006 OIG report using USDA's Pesticide Data Program data found that risks associated with 16 foods commonly eaten by children declined by almost 50 percent due to cancellation actions taken by EPA under FQPA. We found risks declined by about two-thirds in domestically grown foods in 16 important children's foods included in our analysis. Between FQPA implementation in 1996 and 2003, the average Dietary Risk Index values across the 16 domestically produced foods declined from 175 to 65, or about 63 percent.

The GAO issued three reports on exporting unregistered pesticides between 1979 and 1993. The following summarizes the major findings from these GAO reports, as well as one by Carl Smith,

Kathleen Kerr, and Ava Sadripour, which focused on U.S. Customs Service data used to track pesticide product exports, and a USDA report on violations.

Government Accountability Office. ***Pesticides: Limited Testing Finds Few Exported Unregistered Pesticide Violations on Imported Foods.*** **GAO/RCED-94-1, October 1993.**

GAO identified 27 unregistered food-use pesticides manufactured in the United States for export and linked four unregistered pesticides to FDA-cited tolerance violations. GAO found that it was not possible to determine whether all four pesticides responsible for these violations originated from U.S. exports due to difficulties in tracking the use and destination of U.S.-unregistered pesticide exports and foreign production of unregistered pesticides. GAO concluded that information gaps and minimal legislative requirements prevent FDA from testing for residues from U.S. exports of unregistered pesticides that might be returning to this country on imported foods. FIFRA does not require U.S. manufacturers to provide EPA or FDA with samples, test methods, or pesticide-use information for unregistered pesticides.

Government Accountability Office. ***Pesticides: Exports of Unregistered Pesticides is Not Adequately Monitored by EPA*****. GAO/RCED-89-128, April 1989.**

GAO found that EPA has yet to establish an effective program to determine whether pesticide manufacturers are complying with the export notification requirements. EPA does not know whether export notices are being submitted as required under FIFRA. EPA does not have internal procedures for preparing and issuing notices to foreign countries and international organizations when it has taken significant action on a pesticide because of a serious health or environmental concern. GAO found that foreign governments may not be alerted to unreasonable hazards associated with using particular pesticides.

Government Accountability Office. ***Pesticides: Better Regulation of Pesticide Exports and Pesticide Residues in Imported Foods is Essential.*** **GAO/RCED-79-43, June 1979.**

Pesticides suspended, cancelled, or never registered for use in the United States because of hazards associated with their use or unknown health and environmental risks are exported routinely. The EPA in many cases has neither informed other governments of pesticide suspensions, cancellations, and restrictions in the United States nor revoked tolerances for residues of these pesticides on imported food. The safety and appropriateness of some residues allowed on imported food has not been determined.

Smith, Carl, Kathleen Kerr, MD, and Ava Sadripour. "Pesticide Exports from U.S. Ports, 2001–2003." ***International Journal of Occupational Health*** **14, No 3:176–86, July/September 2008.**

Smith et al.'s analysis of U.S. Customs Service records for 2001-2003 indicates that nearly 1.7 billion pounds of pesticide products were exported from U.S. ports, a rate of greater than 32 tons/hour. Exports included greater than 27 million pounds of pesticides whose use is cancelled in the United States. World Health Organization Class 1a and 1b pesticides were exported at an average rate of greater than 16 tons/day. Pesticide exports included greater than 500,000 pounds

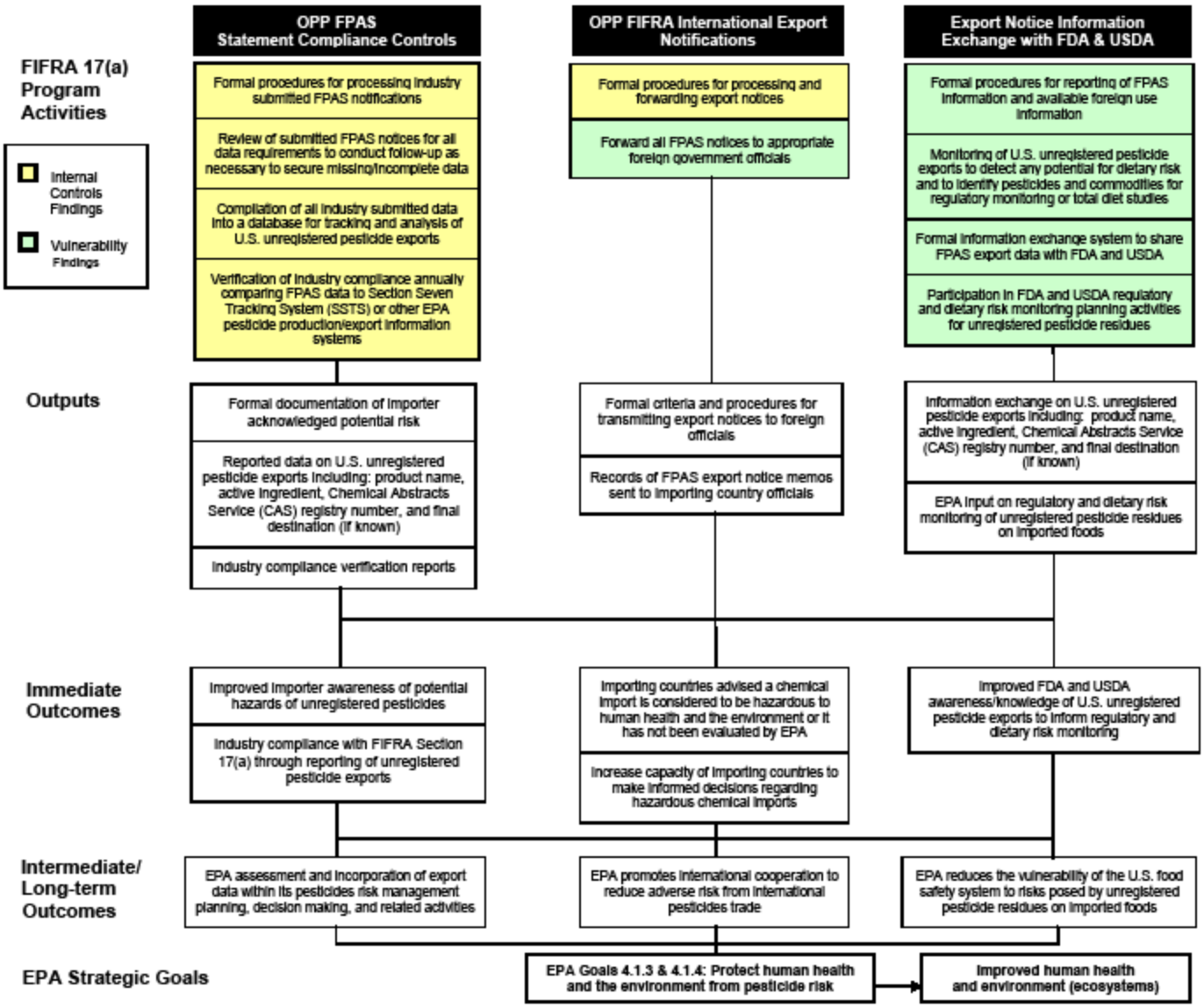
of known or suspected carcinogens, with most going to developing countries; pesticides associated with endocrine disruption were exported at an average rate of greater than 100 tons/day. Although the rate of export of banned products declined, as did exports of pesticides included in global conventions on Prior Informed Consent and Persistent Organic Pollutions, substantial quantities of hazardous products remain in trade. These products pose unacceptable risks in countries where unsafe use and storage practices are prevalent.

Jean C. Buzby, Laurian J. Unnevehr, and Donna Roberts. *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports*. EIB-39. U.S. Department of Agriculture, Economic Research Service, September 2008.

This report examines FDA data on refusals of food offered for importation into the United States from 1998 to 2004. Although the data do not necessarily reflect the distribution of risk in foods, the study found that import refusals highlight food safety problems that appear to recur in trade and where the FDA has focused its import alerts, examinations (e.g., sampling), and other monitoring efforts. The data show some food industries and types of violations are consistent sources of problems, both over time and in comparison with previous studies of more limited data. The three food industry groups with the most violations were vegetables (20.6 percent of total violations), fishery and seafood (20.1 percent), and fruits (11.7 percent). Violations observed over the entire time period include sanitary issues in seafood and fruit products, unsafe pesticide residues in vegetables, and unregistered processes for canned food products in all three industries.

Appendix B

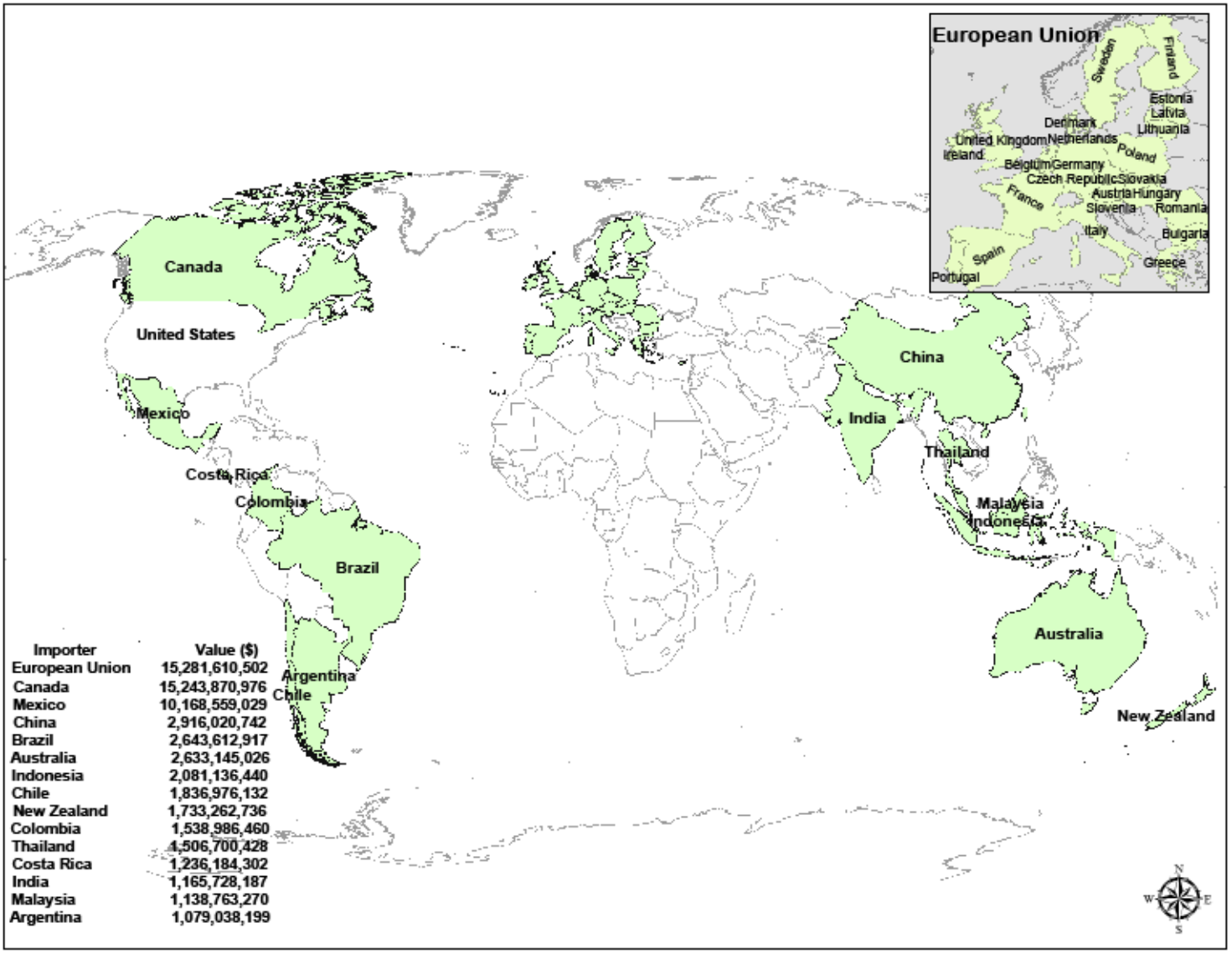
FIFRA 17(a) Programmatic Logic Model of Additional Controls



Source: OIG evaluation of OPP documents.

Appendix C

Map of 2007 Leading U.S. Agricultural Import Sources



Importer	Value ($)
European Union	15,281,610,502
Canada	15,243,870,976
Mexico	10,168,559,029
China	2,916,020,742
Brazil	2,643,612,917
Australia	2,633,145,026
Indonesia	2,081,136,440
Chile	1,836,976,132
New Zealand	1,733,262,736
Colombia	1,538,986,460
Thailand	1,506,700,428
Costa Rica	1,236,184,302
India	1,165,728,187
Malaysia	1,138,763,270
Argentina	1,079,038,199

Source: OIG review of USDA data.

Appendix D

FPASs Received and Forwarded by EPA

Initial Export Destination Country Listed on FPAS	FPAS Received By EPA	FPAS Forwarded By EPA[21]
Albania	3	2
Algeria	5	0
Argentina	36	0
Aruba	1	0
Australia	52	1
Austria	29	3
Azerbaijan	1	0
Bahamas	4	0
Bahrain	1	0
Bangladesh	1	0
Barbados	16	0
Belarus	4	0
Belgium	23	1
Belize	4	1
Bolivia	5	0
Brazil	49	0
Bulgaria	1	0
Cameroon	6	0
Canada	198	0
Cayman Island	3	0
Chile	15	0
China	79	0
Colombia	32	0
Congo	1	0
Congo, DRC	1	0
Costa Rica	46	0
Cote d'Ivoire	9	0
Croatia	1	0
Cyprus	9	2
Czech Republic	9	0
Denmark	2	0
Dominican Republic	27	1
Ecuador	64	6
Egypt	8	0
El Salvador	20	0
Estonia	11	0
Ethiopia	6	0
Fiji	2	0
France	87	4
Georgia	7	0
Germany	97	1
Ghana	5	2
Greece	24	1
Guatemala	31	1
Guyana	1	0
Honduras	19	1
Hungary	14	2
India	30	0
Indonesia	17	0
Iraq	1	0
Ireland	2	0
Israel	13	0
Italy	43	0
Jamaica	5	0
Japan	53	0
Jordan	2	0
Kenya	16	1
Kuwait	1	0
Lebanon	10	2
Macedonia	2	0
Malaysia	11	0
Mexico	101	4
Morocco	14	3
Netherlands	57	4
Netherland Antilles	2	0
New Zealand	23	0
Nicaragua	13	0
Oman	7	1
Pakistan	12	0
Panama	113	2
Paraguay	2	0
Peru	19	0
Philippines	11	0
Poland	12	0
Portugal	14	1
Qatar	2	0
Romania	5	0
Russia	1	0
Saudi Arabia	12	1
Senegal	2	0
Serbia & Montenegro	8	0
Singapore	17	0
South Africa	18	1
South Korea	29	0
Spain	25	3
Sri Lanka	3	0
Suriname	1	0
Sweden	3	0
Switzerland	139	1
Taiwan	26	0
Tanzania	1	0
Thailand	19	0
Trinidad & Tobago	15	1
Tunisia	5	1
Turkey	11	0
Ukraine	20	0
United Arab Emirates	8	0
United Kingdom	172	0
Uruguay	11	0
Venezuela	44	0
Vietnam	5	0

Source: OIG analysis of 2007 FPASs received.

[21] All of the forwarded FPASs were for a particular pesticide: the granular formulations of carbofuran.

Appendix E

Dietary Risk Case Study

To demonstrate the potential threat from an unregistered pesticide and the possible vulnerability of the U.S. food safety system, we developed a case study based on the previous OIG report, *Measuring the Impact of the Food Quality Protection Act*.[22] We compared 2006 FDA violations data to data obtained from the 2007 FPASs to identify U.S. pesticide exports for these pesticide products with corresponding FDA import residue violations. We focused on the pesticides chlorpyrifos and methyl parathion.

Toxicity of Chlorpyrifos and Methyl Parathion

Chlorpyrifos was one of the most widely used insecticides in the United States and was commonly found in many home-and-garden insecticides. In June 2000, EPA released a revised risk assessment and announced an agreement with registrants to phase out and eliminate certain uses of chlorpyrifos. This action eliminated home, lawn, and garden uses by the end of 2000. EPA also cancelled the use of chlorpyrifos on tomatoes and restricted its use on apples.

Methyl parathion is one of the most toxic organophosphate pesticides. EPA's risk assessment showed that methyl parathion posed an unacceptable risk to infants and children. To mitigate the high dietary risk to children, EPA accepted voluntary cancellation of the use of this pesticide on those crops that contribute most to children's diets. These cancelled uses represented 90 percent of the dietary risk to children, dramatically reducing the estimated dietary risk and thus making the risk acceptable for children and all others in the U.S. population.

Federal Monitoring Can Capture Risks from Cancelled Pesticide Residues

EPA's cancellation of the organophosphate pesticides chlorpyrifos and methyl parathion under FQPA reduced 98 percent of the total pesticide dietary risk among U.S. infants and children. Revocation of pesticide tolerances under FQPA shifted risk from domestic to imported foods. Our limited analysis of 2006 FDA-reported tolerance violations for chlorpyrifos and methyl parathion indicates EPA actions on pesticide tolerances under FQPA are also reducing total pesticide dietary risk posed by cancelled pesticide residues on imported foods.

Chlorpyrifos and methyl parathion violative residues together composed 8 percent (18) of the total import violations (217) cited by FDA Pesticide Residue Monitoring Program in FY 2006. Twelve of the 14 violative chlorpyrifos residues found were cited for residues with no EPA-established tolerances for the commodity tested, with the remaining violations for exceeding or meeting the level of current EPA tolerances or FDA formal action levels. FDA cited no EPA

[22] EPA–OIG. *Details on Dietary Risk Data in Support of Report No. 2006-P-00028, "Measuring the Impact of the Food Quality Protection Act: Challenges and Opportunities."* Supplemental Report, August 1, 2006.

established tolerance on the commodity tested for 100 percent of the four violative methyl parathion residues detected.

Primary imported food risk drivers or pesticide-food combinations posing the highest dietary risk to infants and children identified under FQPA include chlorpyrifos on apples, tomatoes, or sweet bell peppers, and methyl parathion on processed green beans. No FDA violations were cited in FY 2006 for these imported pesticide-food combinations. Imported commodities such as spices, exotic fruits, and rice not frequently consumed by infants and children were cited by FDA for lack of EPA established tolerances.

Origins of Chlorpyrifos and Methyl Parathion Pesticide Residues on Imported Foods Difficult to Trace

The 1993 GAO report *Pesticides: Limited Testing Finds Few Exported Unregistered Pesticide Violations on Imported Foods* (see Appendix B) identified 27 unregistered food-use pesticides manufactured in the United States for export in 1990. In those instances in which FDA Pesticide Residue Monitoring Program data cited corresponding violative residues, GAO concluded it was not possible to definitively determine whether the United States was the unregistered pesticides' country of origin from available federal records.

Our review of FPAS export notices submitted to EPA in 2007 identified 13 incidents of U.S. exports of chlorpyrifos with reported destinations of Argentina, Canada, Costa Rica, France, Germany, South Africa, Taiwan, and the United Kingdom. FDA Pesticide Residue Monitoring Program FY 2006 data cited tolerance violations for chlorpyrifos residues on imported commodities originating from mainland China, Chile, Colombia, Ecuador, India, Mexico, and Pakistan. No U.S. exports of methyl parathion were reported to OPP in 2007.

Our analysis found that no 2007 U.S.-produced exports of chlorpyrifos correspond with violative residues on imported foods. Concurring with previous GAO conclusions, we found that establishing the origins of unregistered pesticide residues on imported foods proves difficult for two reasons:

1. It is not possible to track the definitive destinations and use (lifecycle) of all U.S.-produced unregistered exports from available federal records; and
2. Unregistered and never-registered pesticides may be produced in countries other than the United States.

Appendix F

Agency Comments

MEMORANDUM

SUBJECT: OPPTS' Comments on the OIG's Draft Evaluation Report "*EPA Needs to Assess the Risk from Never-Registered Pesticides on Imported Foods*" (Project No. 2008-601)

FROM: Stephen A. Owens, Assistant Administrator
Office for Prevention Pesticides and Toxic Substances

TO: Bill A. Roderick, Acting Inspector General
Office of Inspector General

Thank you for the opportunity to comment on the draft evaluation report, dated August 10, 2009, by the Office of Inspector General (OIG) entitled "*EPA Needs to Assess the Risk from Never-Registered Pesticides on Imported Foods*," Project No. 2008-601.

From our review of the draft report, it appears that the OIG's conclusions regarding possible risks to consumers from imported foods flow from the OIG's analysis of the 2,281 Foreign Purchaser Acknowledgement Statements (FPASs) of exports filed with OPP in 2007. The Federal Insecticide, Fungicide, and Rodenticide Act requires industry to submit FPASs to EPA for all exports of pesticide products/formulations not registered for use in the U.S. The OIG draft report asserts that of these 2,281 FPASs "182 FPAS received by EPA were for pesticides with chemical components that were never registered in the United States. The risk associated with these products is unknown because the human and environmental hazards have not been evaluated by EPA."

To verify the accuracy of OIG's data review, OPP conducted a detailed evaluation of the 182 FPASs in question. OPP's analysis shows a very different factual situation. We share a common interest in the report's conclusions being based upon the most accurate information available. Therefore, we share the following analysis. OPP found that 180 of these FPASs:

1. were for products containing active ingredients that had either been registered by EPA (often of a different product formulation) and/or had tolerances or specific exemptions from tolerance requirements for residues in food, or
2. were for pesticides still in the research and development stage, or
3. were not pesticides.

FPASs are not required for these last two categories. Therefore, of the 182 FPASs cited in the draft report, only two were for products with active ingredients that do not have a U.S. registration, tolerance, or exemption. These two pesticide products have active ingredients that have maximum residue limits (tolerances) and have been registered for use in the European

Union based on an evaluation of the human and environmental hazards. Thus, the OIG's conclusion about potentially significant unknown risks from pesticides which EPA has not evaluated, and FDA cannot detect on imported foods, is not supported by the available information on these exports.

With regard to the case study in Appendix F, the authors write that they developed this case study to "demonstrate the potential threat from an unregistered pesticide and the possible vulnerability of the U.S. food supply." OPPTS notes that both pesticides (active ingredients) used in this scenario have EPA registrations and tolerances for which we have completed risk assessments. Our assessments include consideration of consuming domestic and imported foods with residues of these pesticides.

We believe it would be useful to come to a common understanding of the facts before proceeding further with consideration of next steps and determining the most promising way forward in terms of enhancing our pesticide/food safety programs. We would be happy to meet again with your staff to review our analyses of the data in greater detail together, with the goal of reaching agreement on the baseline for future improvements.

Appendix G

Agency Comments and OIG Evaluation

MEMORANDUM

SUBJECT: OPPTS' Comments on the OIG's Draft Evaluation Report "*EPA Needs to Assess the Risk from Never-Registered Pesticides on Imported Foods*" (Project No. 2008-601)

FROM: Stephen A. Owens, Assistant Administrator
Office for Prevention Pesticides and Toxic Substances

TO: Bill A. Roderick, Acting Inspector General
Office of Inspector General

Thank you for the opportunity to comment on the draft evaluation report, dated August 10, 2009, by the Office of Inspector General (OIG) entitled "*EPA Needs to Assess the Risk from Never-Registered Pesticides on Imported Foods*," Project No. 2008-601.

OIG Response: The Agency's comments on the draft report are nonresponsive. The Agency's response does not address the findings and recommendations presented in this report. We concluded that EPA is not complying with FIFRA 17(a) which is, in part, intended to notify the government of an importing country that a potentially hazardous pesticide has been exported and is not registered and cannot be sold for use in the United States. We found EPA does not determine manufacturer compliance with FIFRA Section 17(a) notification requirements. Furthermore, EPA has decided not to comply with statutory requirements to provide notice to all countries importing unregistered pesticides. The Agency's response does not address these findings or the related recommendations.

From our review of the draft report, it appears that the OIG's conclusions regarding possible risks to consumers from imported foods flow from the OIG's analysis of the 2,281 Foreign Purchaser Acknowledgement Statements (FPASs) of exports filed with OPP in 2007.

OIG Response: Only a portion of Chapter 3, not the whole report, addresses the possible risks to consumers based on the FPAS analysis. The conclusion regarding possible risks to consumers from imported foods was based on an analysis of the roles and responsibilities of EPA in ensuring the safety of imported foods, as described in Appendix B. Our analysis included a review of the universe of the 2,291 FPASs received by EPA for 2007; mining of an internal and external database; a review of the federal monitoring program; meetings with FDA, USDA, agency staff; and a review of Agency policies and practices. Moreover, Chapter 2 of the report addresses Agency noncompliance with the requirements of FIFRA.

The Federal Insecticide, Fungicide, and Rodenticide Act requires industry to submit FPASs to EPA for all exports of pesticide products/formulations not registered for use in the

U.S. The OIG draft report asserts that of these 2,281 FPASs "182 FPAS received by EPA were for pesticides with chemical components that were never registered in the United States. The risk associated with these products is unknown because the human and environmental hazards have not been evaluated by EPA."

To verify the accuracy of OIG's data review, OPP conducted a detailed evaluation of the 182 FPASs in question. OPP's analysis shows a very different factual situation. We share a common interest in the report's conclusions being based upon the most accurate information available.

OIG Response: OPP's need to conduct a detailed evaluation to address the 182 FPAS in this report illustrates our conclusion that the Agency's control processes are inadequate. The fact that OPP's subsequent review did not disclose a serious risk is not proof that a risk will never exist or that a control process is unnecessary. It only demonstrates that EPA would have been unaware if one of the 182 had posed a major risk because of these insufficient control mechanisms.

The assessment the OIG performed on the FPAS universe was completed with information available at the time of our review. In assessing product status, we checked OPP's internal Office of Pesticide Programs Information Network (OPPIN) database using a variety of different search parameters. We also used the external Pesticide Action Network database to confirm our results. OPP's lack of quality assurance and quality control mechanisms for FPAS data caused a number of problems in accurately assessing the status for each product. For example, OPP reports that some of the 182 FPASs were for nonpesticide products. There apparently were no control mechanisms in place to reject FPASs received for nonpesticides. In addition, FPAS information lacks data integrity controls to ensure that product names are spelled correctly and active ingredients are properly listed. These two data items are imperative to accurately assessing product status, and therefore resulted in disparities between our results and OPP's.

Therefore, we share the following analysis. OPP found that 180 of these FPASs:

1. were for products containing active ingredients that had either been registered by EPA (often of a different product formulation) and/or had tolerances or specific exemptions from tolerance requirements for residues in food, or
2. were for pesticides still in the research and development stage, or
3. were not pesticides.

FPASs are not required for these last two categories.

OIG Response: The 182 FPASs that OPP refers to are a subset of the 2,291 FPASs received by EPA during the calendar year 2007. If many of the 182 FPASs OPP reviewed in response to our draft report have now been identified as nonpesticides, that is an indication that the overall system is flawed. FIFRA Section 17(a) requires that before an unregistered pesticide is exported from the United States, the foreign purchaser must sign a statement acknowledging an awareness that the pesticide is not registered and cannot be sold for use in the United States. The pesticide exporter is then required to transmit an FPAS for the pesticide product to EPA certifying that the

FPAS preceded the initial shipment. According to OPP, it appears that some of the FPASs may be for chemicals that are not pesticides and therefore should not require an FPAS. OPP needs to take steps to ensure the process used by manufacturers is meeting the intent of FIFRA, which is to notify the government of importing countries that a potentially hazardous **pesticide** has been exported and is not registered and cannot be sold for use in the United States.

OPP's analysis further supports our finding that EPA does not determine manufacturer compliance with FIFRA Section 17(a) notification requirements. Not only may EPA not be receiving FPASs for unregistered pesticides, but some FPASs may be issued for nonpesticides. Therefore, the true universe of unregistered pesticides being exported, along with the associated risk, is unknown. In addition, EPA is creating an additional burden for itself and foreign governments by receiving, cataloging, and potentially forwarding unnecessary FPASs. The Agency's analysis provides significant evidence that an internal review of FPAS data would provide both the Agency and external stakeholders with a more accurate depiction of pesticide exports.

Therefore, of the 182 FPASs cited in the draft report, only two were for products with active ingredients that do not have a U.S. registration, tolerance, or exemption. These two pesticide products have active ingredients that have maximum residue limits (tolerances) and have been registered for use in the European Union based on an evaluation of the human and environmental hazards.

OIG Response: As we stated in Chapter 3, the extent of dietary risk from never-registered pesticide residues on imported foods is unknown. The unknown risk is due in part to the unknown nature of the universe of never-registered pesticides. This type of belated review conducted by OPP in response to our draft report is the analysis that would be required for all FPASs received in order to fully address the intent of the recommendations in Chapter 3. At the time of our evaluation, OPP did not have information on the risk associated with the chemicals on the FPASs because reviews such as this were not being conducted.

Thus, the OIG's conclusion about potentially significant unknown risks from pesticides which EPA has not evaluated, and FDA cannot detect on imported foods, is not supported by the available information on these exports.

OIG Response: As discussed previously, OPP's retrospective evaluation of the 182 FPAS demonstrates our conclusion that the Agency's control processes and environment are deficient. We concluded that EPA's current practices are insufficient to monitor for the potential re-entry of never-registered pesticides on imported foods or to determine whether a dietary risk to U.S. consumers exists. The safety of unregistered pesticides intended solely for export is not evaluated by EPA, and EPA does not know the pesticide class, volume, use, or final destination of unregistered U.S. pesticide exports. Consequently, EPA cannot provide FDA and USDA with information needed to monitor and detect pesticide residues from never-registered pesticides.

With regard to the case study in Appendix F, the authors write that they developed this case study to "demonstrate the potential threat from an unregistered pesticide and the possible vulnerability of the U.S. food supply." OPPTS notes that both pesticides (active ingredients)

used in this scenario have EPA registrations and tolerances for which we have completed risk assessments. Our assessments include consideration of consuming domestic and imported foods with residues of these pesticides.

OIG Response: As explained in Appendix E (Appendix F in an earlier version of this report), we compared 2006 FDA violations data to data obtained from the 2007 FPASs in order to identify U.S. pesticide exports for these pesticide products with corresponding FDA import residue violations. As highlighted in the report, the Federal Government does not have the capability to detect pesticides that have never been registered in the United States. Therefore, in order to conduct this analysis, we had to choose pesticides that are monitored and can be detected by FDA.

According to the Agency, unregistered pesticides include pesticides that have been registered and are now cancelled. We chose to focus on two cancelled pesticides, chlorpyrifos and methyl parathion, because of the information OPP has on those pesticides. The intent of the analysis was to explain how well OPP's system of regulating dietary risk works when the Office has complete information regarding a pesticide product or active ingredient. In order to conduct such an analysis, we used pesticides for which EPA has complete regulatory data and extensively reviewed. Our analysis showed the reduction in dietary and nondietary risk from regulatory actions taken by OPP for the active ingredients we assessed. The last section on tracking simply highlights the difficulties faced by OPP in correlated dietary exposure on imported foods. It does not dispute our findings regarding the reductions in dietary risk from OPP regulatory actions.

We believe it would be useful to come to a common understanding of the facts before proceeding further with consideration of next steps and determining the most promising way forward in terms of enhancing our pesticide/food safety programs. We would be happy to meet again with your staff to review our analyses of the data in greater detail together, with the goal of reaching agreement on the baseline for future improvements.

Appendix H

Distribution

Office of the Administrator
Assistant Administrator for Prevention, Pesticides and Toxic Substances
Agency Follow-up Official (the CFO)
Agency Follow-up Coordinator
General Counsel
Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for Public Affairs
Audit Follow-up Coordinator, Office of Prevention, Pesticides and Toxic Substances
Acting Inspector General