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

FEB 25 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to December 15, 2010 Final Evaluation Report,
"EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products"
Report No. 11-P-0029

FROM: Stephen A. Owens, Assistant Administrator
Office of Chemical Safety and Pollution Prevention

TO: Arthur A. Elkins, Jr.
Inspector General

This memorandum is in response to the Office of Inspector General's (OIG) December 15, 2010, Final Evaluation Report, entitled *EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products* (Report No. 11-P-0029) ("Final Report"), which evaluated the Agency's Antimicrobial Testing Program (ATP). The Office of Chemical Safety and Pollution Prevention (OCSPP) appreciates the OIG's efforts to review the ATP, and its interest in improving the program. The Agency agrees with the OIG that the program should be redesigned and concurs with some of the OIG findings. As the OIG acknowledges in the report, OCSPP has already initiated several program improvements, and will continue that work.

As required by EPA Order 2750, "EPA's Audit Management Process," we are submitting along with this memorandum a corrective action plan to address the OIG's recommendations. Below is an overview of the corrective actions proposed for each recommendation; the attached corrective action plan provides the specific due dates.

As you know, the Final Report recommended that the Assistant Administrator for Chemical Safety and Pollution Prevention take the following actions:

1. *Redesign the process used to verify antimicrobial effectiveness. Specifically, we recommend a new program design that includes:*

   Recommendation 1-a: *A testing program to provide reasonable assurance of the efficacy of currently registered tuberculocides and hospital-level disinfectants by the end of 2011. Subsequently registered products should be subject to same program.*

OCSPP Response: OCSPP agrees with the above recommendation, has completed a number of actions, and has additional actions planned to provide reasonable assurance of the efficacy of currently registered tuberculocides and hospital-level disinfectants by the end of 2011. For example, EPA has developed an improved product tracking system and will make expanded product status information publicly available. The attached Corrective Action Plan lists other actions, some of which have been completed, to implement this recommendation.

Recommendation 1-b: *An efficient sampling protocol that enables regulatory and enforcement actions as appropriate.*

OCSPP and OECA Response: OCSPP and OECA agree with this recommendation. On September 27, 2010, OECA issued a revised Antimicrobial Testing Program Sample Collection Protocol. The revised protocol covers the collection of products by EPA and State inspectors. OECA also provided additional guidance on the collection of products in the marketplace. For FY 2011, OECA's Office of Compliance has made a number of changes to the procedure to ensure a more efficient process. These changes include preliminary screening of the list of products to be collected against pesticide production information, and also additional research to identify where the product to be collected might be found in the marketplace. Another improvement that we believe will help the sample collection process is the appointment of an ATP coordinator in each EPA regional office. If an inspector has difficulty locating a sample, he or she will work with the regional coordinator to resolve the issue.

Recommendation 1-c: *Consistent implementation, communication, and follow-up of enforcement actions by EPA regions.*

OECA Response: EPA uses the Federal Insecticide, Fungicide, and Rodenticide Act Enforcement Response Policy (FIFRA ERP), www.epa.gov/compliance/resources/policies/civil/fifra/fifra-erp1209.pdf , as the implementing document to determine the appropriate enforcement response and penalty to be assessed for violations. EPA's enforcement professionals use the FIFRA ERP as a guide in considering the facts and circumstances of each case and the company's compliance history to ensure an enforcement response appropriate for the particular violations. The policy is designed to allow swift resolution of environmental problems, deter future violations, and to provide a framework for consistent enforcement response across the nation. The current FIFRA ERP was issued in December 2009 to update and improve consistency in the FIFRA enforcement program.

Since most of the regional enforcement response inconsistencies referenced in the OIG Audit Report were based on enforcement responses taken under the prior FIFRA ERP, OECA believes that use of the updated and revised FIFRA ERP has addressed those inconsistencies. Nevertheless, due to the significant changes incorporated into the updated FIFRA ERP and the on-going need to provide training on how to implement certain new aspects of the policy (such as a graduated penalty provision and enhanced provisions to capture the economic benefit of noncompliance), OECA intends to review

the ERP during FY 2011 and make further adjustments, as may be necessary, to facilitate effective and consistent utilization of the ERP. OECA expects to complete that review and revision by December 31, 2011.

In addition, OECA has procedures in place that govern enforcement actions involving issues of national significance. This process is used to implement a consistent enforcement response when nationally significant issues are involved and provides an additional level of Headquarters interaction and oversight on applicable regional enforcement actions.

OECA communicates enforcement actions with external stakeholders through press releases and the OECA website. OCSPP and OECA will continue to work with EPA's headquarters and regional press and outreach offices on the most appropriate way to notify communities of failed antimicrobial products.

Consistent follow-up of enforcement penalty actions by the regions and OECA is accomplished by making sure that the violator has paid the stipulated penalty. Once an enforcement action is taken, all enforcement related data are entered into the Integrated Compliance Information System (ICIS) for tracking purposes. ICIS tracks these actions by company name, enforcement action date(s), and law section(s) violated. Additional monitoring is done through follow-up inspections of pesticide producer establishments and other wholesale and retail distributor facilities as a part of routine assignments under a neutral inspection scheme.

Recommendation 1-d: *A testing program to provide reasonable assurance of the efficacy of registered sanitizers.*

OCSPP Response: OPP has undertaken a management effectiveness review, referred to as the "LEAN Review of the ATP," to increase the efficiency and effectiveness of product collection, testing, and the resolution of product failures. Part of the LEAN Review involves examining the long-term structure and scope of the ATP. When the LEAN Review has been completed, the ATP LEAN Committee will send a memo to OPP's Office Director regarding recommendations on the future structure of ATP.

Please know that my staff and I, in addition to our colleagues in the Office of Enforcement and Compliance Assistance, remain committed to being responsive to the recommendations contained in the report "EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products." If you have any questions regarding the attached corrective action plan, or if you believe further dialogue would benefit the review process for plan, please have your staff contact Janet L. Weiner of the OCSPP IO, Resources Management Staff, at (202) 564-2309.

Attachment: Corrective Action Plan

cc: Wade T. Najjum, Assistant Inspector General for Program Evaluation
Jeffrey Harris, Director for Cross-Media Issues, Office of Program Evaluation, OIG
Cynthia Giles, Assistant Administrator for Enforcement and Compliance Assistance

Corrective Action Plan
Response to the OIG Final Evaluation Report:
"EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products (Report No. 11-P-0029)"

Recommendation	Action	Deliverable	Lead Office/Division	Goals	Status/ Schedule for Completion
1(a): A testing program to provide reasonable assurance of the efficacy of currently registered tuberculocides and hospital-level disinfectants by the end of 2011. Subsequently registered products should be subject to same program	Develop improved product tracking system and make product status publicly available	Internal Tracking Database	OPP/Biological and Economic Analysis Division(BEAD)	A system that measures, manages, and monitors status of all products	August 9, 2010 COMPLETED
		Website – updated http://www.epa.gov/oppad001/antimicrobial-testing-program.html#results	OPP/Information Technology and Resource Management Division (ITRMD), Antimicrobial Division (AD), and BEAD	Help reduce time it takes for information to get to public. Provide information to industry about the status of their products.	October 15, 2010 COMPLETED
		Public Health Tracking System	ITRMD	A system that measures, manages, and monitors status of all products and ECRs	May 31, 2011 Test System July 29, 2011 Production System

Corrective Action Plan **Response to the OIG Final Evaluation Report:** **"EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products (Report No. 11-P-0029)"**					
Recommendation	Action	Deliverable	Lead Office/Division	Goals	Status/ Schedule for Completion
1(a): continued		Collect products currently in production that were not picked up through the voluntary shipment program	AD, OECA and Regions	Assure efficacy of currently registered products	December 31, 2010 COMPLETED
		Collect any products currently in production that were not picked up through either the voluntary shipment program and/or the 2010 inspector collection	AD, OECA and Regions		May 31, 2011
		Begin collecting newly registered (FY10 and early FY11) products currently in production	AD, OECA and Regions		May 31, 2011 (Note: collection of newly registered products for testing will continue past close-out of this deliverable.)
		Collect products currently in production that need to be retested	AD, OECA and Regions		July 29, 2011

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Recommendation	Action	Deliverable	Lead Office/Division	Goals	Status/ Schedule for Completion
1(b): An efficient sampling protocol that enables regulatory and enforcement actions as appropriate	Develop revised Antimicrobial Testing Program Sample Collection Protocol	Revise ATP Sample Collection Protocol	OECA	Provide guidance on collection of products by EPA and State inspectors	September 27, 2010 COMPLETED
	Establish regional ATP coordinators	Identify Regional ATP Coordinators	OECA	Ensure more efficient and coordinated process for sample collection	September 27, 2010 COMPLETED
	Follow-up on products which fail efficacy testing	Revise ATP Failure Letter to registrants which identifies options for compliance with the letter and provides tight time frames for response and corrective actions	AD	Reduce time to follow-up on failures	January 2011 COMPLETED
		Revise SOP for referral of products failing efficacy testing for either enforcement or regulatory action	AD		September 30, 2011

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Recommendation	Action	Deliverable	Lead Office/Division	Goals	Status/ Schedule for Completion
1(c): Consistent implementation, communication, and follow-up of enforcement actions by EPA regions	Develop and issue an updated FIFRA Nationally Significant Issues Policy (NSI)	Revised FIFRA NSI Policy	OECA	Ensure consistent enforcement response on issues of national significance	June 2011
	Use the revised FIFRA Enforcement Response Policy (ERP) more consistently	Review FIFRA ERP and revise as necessary Note: The current ERP was updated/revised December 2009. However, due to the amount of significant changes incorporated into the document, this ERP will be reviewed again and revised as necessary to ensure its effective and consistent utilization	OECA	Ensure appropriate enforcement responses	December 31, 2011 Review the FIFRA ERP and revise as necessary
1(d): A testing program to provide reasonable assurance of the efficacy of registered sanitizers	Re-evaluate Antimicrobial Testing Program process and scope	Memo from ATP LEAN Committee to OPP Office Director regarding recommendations on the future structure of ATP	AD and BEAD	Ensuring the effectiveness of registered products	September 30, 2011