U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

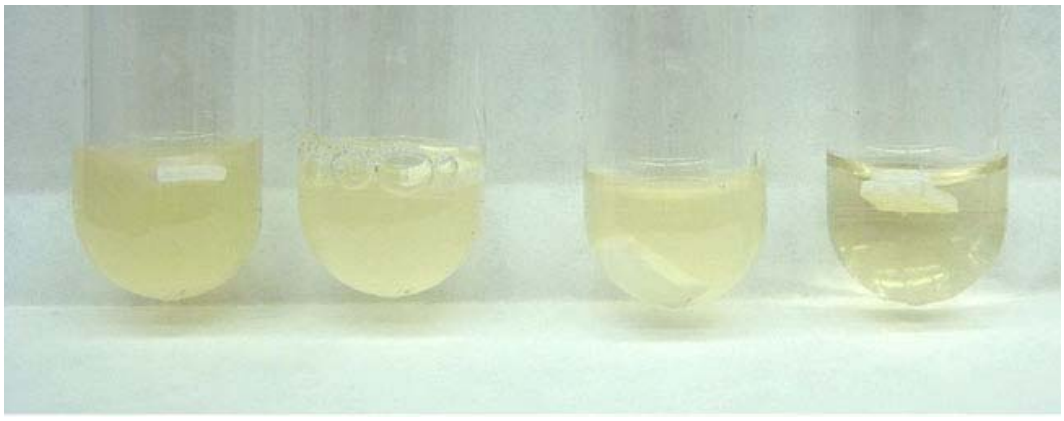
Catalyst for Improving the Environment

Hotline Report

Results of Hotline Complaint Review of EPA's Antimicrobial Testing Program

Report No. 09-P-0152

May 27, 2009



Report Contributors: Stacey Bond
Ganesa Curley
Jerri Dorsey
Jeffrey Harris
Lauretta Joseph

Abbreviations:

ATP	Antimicrobial Testing Program
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FY	Fiscal Year
OECA	Office of Enforcement and Compliance Assurance
OIG	Office of Inspector General
OPP-AD	Office of Pesticide Programs--Antimicrobial Division
SOP	Standard Operating Procedure

Cover photo: The cloudy liquids in three of these test tubes show that bacteria have started growing. The one tube with clear liquid contains a surface coated with penicillin; this new method, developed by researchers at The University of Southern Mississippi, prevents bacteria from growing in the tube. (Credit: The University of Southern Mississippi)

U.S. Environmental Protection Agency
Office of Inspector General

09-P-0952
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At a Glance

Catalyst for Improving the Environment

Why We Did This Review

The Office of Inspector General (OIG) received a Hotline complaint that alleged that EPA is withholding information on product failures in the Antimicrobial Testing Program (ATP) from intended users.

Background

The EPA's Office of Pesticide Programs--Antimicrobials Division (OPP-AD) is responsible for all regulatory activities associated with antimicrobial pesticides. A key project of OPP-AD is the ATP, the post-registration testing program designed to evaluate the effectiveness of EPA-registered disinfectants. The focus of the ATP is on disinfectants most crucial to infection control: sterilants, tuberculocides, and hospital-level disinfectants.

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/2009/20090527-09-P-0152.pdf

Results of Hotline Complaint Review of EPA's Antimicrobial Testing Program

What We Found

We found that the allegation against EPA's ATP was unsubstantiated. The program policies and procedures require OPP to notify the Office of Enforcement and Compliance Assurance (OECA) and manufacturers when a product fails testing. OPP-AD is not withholding information on product failures from these intended users. As of February 2009, 325 of the 671 EPA registered disinfectant products had been tested under the ATP. ATP anticipates completing efficacy testing of all currently registered disinfectant products by 2011.

The OPP-AD procedures specify what type of action is to be taken based on testing results. When a product fails, OPP-AD follows its Standard Operating Procedure (SOP) for product failures. OPP-AD decides whether a regulatory or enforcement action should be pursued for products that fail. OECA makes the final decision regarding any enforcement actions to be taken against manufacturers.

The report does not contain any recommendations; however, we make several observations regarding OPP policies and practices that could be improved. OPP-AD could:

- provide publicly-accessible information on effective hospital disinfectants and tuberculocidal products as it does with other disinfectants.
- amend its SOPs to include products without a hospital disinfectant label claim.
- develop a plan to sustain the program after testing is completed in 2011.

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

OFFICE OF
INSPECTOR GENERAL

May 27, 2009

MEMORANDUM

SUBJECT: Results of Hotline Complaint Review of EPA's Antimicrobial Testing Program
Report No. 09-P-0152

FROM: Wade T. Najjum
Assistant Inspector General
Office of Program Evaluation

TO: Jim Jones
Acting Assistant Administrator
Office of Prevention, Pesticides, and Toxic Substances

This is our Hotline report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains our finding regarding the Hotline allegation. The report does not contain any recommendations; however, the OIG makes several observations regarding Office of Pesticide Programs policies and practices that could be improved. The OIG's review of this Hotline complaint is completed with the issuance of this report.

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 $89,833

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 najjum.wade@epa.gov; Jeffrey Harris, Director of Cross Media Issues, at 202-566-0831 or harris.jeffrey@epa.gov; or Lauretta Joseph, Project Manager, at 212-637-3049 or ansah.lauretta@epa.gov.

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Purpose

The Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA) receives Hotline complaints of fraud, waste, and abuse within EPA programs and operations. These complaints include mismanagement or violations of law, rules, or regulations reported by EPA employees, program participants, and the general public. In October 2008, the OIG received an allegation against EPA's Antimicrobial Testing Program (ATP). The complaint alleged that EPA was withholding information on high failure rates for hospital disinfectants and tuberculocial products from intended users. Based on information provided in the complaint, our objective was to determine whether EPA is withholding information on product failures from intended users.

Background

Antimicrobial pesticides are substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms on inanimate objects and surfaces. Disinfectants, in particular, are used on hard inanimate surfaces and objects to destroy or irreversibly inactivate infectious fungi and bacteria. The EPA Office of Pesticide Programs-Antimicrobials Division (OPP-AD) is responsible for all regulatory activities associated with antimicrobial pesticides. These activities include evaluating and registering products. A key project of OPP-AD is ATP, the post-registration regulatory program designed to evaluate the effectiveness of EPA-registered disinfectants. The focus of the ATP is on disinfectants most crucial to infection control: sterilants, tuberculocides, and hospital disinfectants. As of February 2009, EPA had registered 671 disinfectant and tuberculocidal products. Of those registered products, EPA has tested 325. OPP expects to complete efficacy testing of all currently registered products in 2011.

According to OPP-AD, products are selected for efficacy testing annually. Samples are collected directly from a manufacturer[1] by EPA regional or State inspectors, or purchased directly from the marketplace. Testing is conducted by the OPP Microbiology Lab in Maryland and three State-contracted Department of Agriculture laboratories, in Michigan, North Carolina, and Ohio. To evaluate products, ATP utilizes standard testing methods from the Association of Official Analytical Chemists.

To evaluate hospital disinfectant product effectiveness, a "60 carrier" use-dilution test is used. To "pass" the test, no more than one of 60 contaminated test surfaces can show growth by the target microorganism after product treatment. If a product passes efficacy testing, the Agency sends a letter to the manufacturer which contains a copy of each product's test results. If the product fails testing, either a regulatory or enforcement action is taken. Table 1 shows the type of action based on the number of test failures.

[1] A manufacturer can be the owner, operator, or agent of the producing establishment.

Table 1: ATP Action Based on Hospital Disinfectant Test Results

Failures (out of 60)	Type of Action
≤ 1	Manufacturer Notification
2-3	Manufacturer Notification and Regulatory Options
4+	Manufacturer Notification and Enforcement Options*

*OECA makes the final decision regarding any enforcement action
Source: OPP-AD

If two or three failures occur, the manufacturer is notified and the product is referred for regulatory action. According to OPP-AD procedures, regulatory actions can be (1) a change to a product label claim, or (2) a retest by the manufacturer under different conditions, using an independent lab, or (3) a retest of a reformulated product. Options for bringing the product into compliance are sent to the manufacturer via a memo sent from an OPP-AD Product Manager. The manufacturer has 45 days to respond to the memo or the product can be suspended or cancelled under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 6.

If four or more failures occur, the product is referred for an enforcement action. Per its procedures, OPP-AD sends OECA a product evaluation report and an enforcement case review. OECA analyzes this information to determine whether the evidence is sufficient to support an enforcement action. According to OECA, enforcement actions may also result in a range of options, including Stop, Sale, Use, or Removal Orders and civil administrative complaints. Enforcement actions from OECA can result in a press release to the general public concerning the product.

Prior Reviews

In 2007, the OIG report, *EPA Did Not Properly Process a Hospital Disinfectant and Sanitizer Registration*, No. 2007-P-00018, found that OPP-AD accepted registrants' submitted label claims that were supported by appropriate data and did not conduct its own pre-registration efficacy testing. The OIG further noted that 2005-2006 efficacy testing results available to the Agency indicated a 40 percent failure rate for tuberculocidal products and a 29.5 percent failure rate for hospital disinfectants. The OIG recommended that OPP-AD perform a detailed root cause analysis to identify why EPA-registered products fail post-registration efficacy testing. According to OPP-AD, the root cause analysis was conducted and the action items noted are being addressed.

Scope and Methodology

We conducted our work from February to March 2009. We conducted our work in accordance with generally accepted government auditing standards unless otherwise noted. These standards require that we plan and perform our review 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 on our objective. An assessment of management or internal controls was not relevant to this review and therefore was not conducted.

In this review, we defined intended users as those notified of product failures in OPP-AD's procedures: manufacturers, OPP, and OECA. Notification of product consumers (i.e. hospitals, nursing homes, and other health care facilities) is not addressed in OPP-AD procedures and was therefore not within our scope.

To accomplish our objectives, we:

- Reviewed OPP-AD policies and procedures for conducting product labeling compliance (efficacy testing);
- Reviewed OPP-AD Standard Operating Procedures (SOPs) for product failures and resulting enforcement actions;
- Interviewed ATP staff at Headquarters to discuss policies and procedures related to testing failures and enforcement actions;
- Reviewed and analyzed FY (fiscal year) 2008 ATP efficacy testing results for hospital disinfectants and tuberculocial products (16 products tested); and
- Tracked ATP actions following FY 2008 test failures to determine if OPP withheld information about failed products from intended users.

The review focused on determining whether information was being withheld and therefore was not a full assessment of the efficiency and effectiveness of ATP.

Results of Review

EPA Is Not Withholding Information on Product Failures from Intended Users

We found that EPA is not withholding information on efficacy testing results of hospital disinfectant and tuberculocidal products from intended users. OPP-AD's policies and procedures require intended users (OECA, OPP, and manufacturers) to be notified when a product fails efficacy testing. Our review of seven product failures in FY 2008 found that OPP-AD followed its SOP for product failures by recommending designated regulatory or enforcement actions. OPP-AD procedures specify what type of action is to be taken based on testing results.

OPP-AD Could Further Improve Its Procedures

OPP-AD staff indicated that the program is in transition. The program is now exploring new options to increase program capacity for sample collection. OPP-AD staff also indicated that the program is developing a database to track efficacy test results. The database is scheduled to be available in 2009. In addition to these improvements, we found that OPP-AD could further improve its procedures.

We observed that OPP-AD does not maintain a comprehensive Website listing of tested EPA-registered effective hospital disinfectants and tuberculocidal products as it does with other disinfectants. For example, a listing of selected EPA-registered effective disinfectants targeting HIV-1 and the Hepatitis B virus are publicly available on EPA's Website.[2] Additionally, we

[2]http://www.epa.gov/oppad001/chemregindex.htm

observed that OPP-AD does not have a SOP for products that are tested as hospital disinfectants but do not have a hospital disinfectant label claim. Moreover, OPP-AD staff stated that the ATP program plans to finish efficacy testing of all currently EPA-registered hospital disinfectants and tuberculocides by 2011. However, OPP-AD workplans do not state what they will do with the results of its testing program or what will happen to the program after 2011.

Conclusion

We found that the allegation against EPA was unsubstantiated. We found no evidence of withholding information per OPP-AD's established procedures. When a product fails, OPP-AD follows its SOP for product failures. The SOP requires OPP-AD to notify applicants (manufacturers), OECA, and OPP of efficacy testing results. We also found that OPP-AD could improve its procedures. OPP-AD could provide publicly accessible information on effective hospital disinfectants and tuberculocidal products, amend its SOPs to include products without a hospital disinfectant label claim, and develop a plan for the program after completing efficacy testing in 2011.

Agency Responses and OIG Evaluation

The Office of Pesticide Programs agreed with our finding and is addressing our suggestions. The Agency's comments and the OIG's evaluation of those comments are in Appendix A. OPP and OECA both provided additional technical comments. We made revisions to the report as appropriate.

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
		No recommendations					

[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

Agency Comments and OIG Evaluation

The Agency response to our draft report consisted of a transmittal memorandum from OPP and OECA. Below we provide our evaluation of the Agency's main points discussed in its transmittal memorandum.

MEMORANDUM

SUBJECT: Comments on the Draft Hotline Report "Results of Hotline Complaint Review of EPA's Antimicrobial Testing Program, Project No. OPE-FY09-0006 April 22, 2009"

FROM: Debra Edwards, Ph.D.
Director, Office of Pesticide Programs

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

This memorandum responds to your request for a response to the draft report prepared by the Office of the Inspector General, which investigated a Hotline Complaint that the Office of Pesticide Programs (OPP) is withholding from intended users information on antimicrobial pesticide product failures identified through the Antimicrobial Testing Program (ATP).

The draft report concludes that the allegation was unsubstantiated and that information is not being withheld from intended users and I concur with this finding. As noted in the report, OPP has SOPs in place that address internal and external communication of ATP actions.

The draft report further stated that the Program could provide publicly-accessible information on effective hospital disinfectants and tuberculocidal products as it does with other disinfectants. We concur, and OPP is in the process of posting on the web all ATP results covering the eighteen-year program history. In the near future, we plan to make the ATP web page publicly accessible to a broad user community including hospitals, nursing homes, and other health care facilities. This is in addition to our responsibility under the Federal Insecticide, Fungicide, and Rodenticide Act, which requires the owner, operator, or agent in charge of any inspected establishment where a sample was collected for testing to be furnished with a copy of the analysis results if the collected sample is analyzed. The report also suggested that OPP develop a plan to sustain the program after testing is completed. OPP is already in the process of developing a strategy that will move the program forward, taking into consideration all the various aspects of the program and the entities involved, to help build a more robust and sustainable post-market disinfectants testing program.

We have provided factual corrections as track changes on the attached draft document and e-mailed a Microsoft Word version of this memorandum and the track changes to ansah.lauretta@epa.gov as requested. If you have questions, do not hesitate to contact me or Marty Monell at (703) 305-7090.

Attachment

MEMORANDUM

SUBJECT: Response to the Office of the Inspector General's Draft Hotline Report, "Results of Hotline Complaint Review of EPA's Antimicrobial Testing Program," Project No. OPE-FY09-0006 (April 22, 2009)

FROM: Catherine R. McCabe
Acting Assistant Administrator

TO: Jim Jones
Acting Assistant Administrator
Office of Prevention, Pesticides, and Toxic Substances

This memorandum is OECA's response to the draft Office of Inspector General (OIG) Hotline Report, "Results of Hotline Complaint Review of EPA's Antimicrobial Testing Program." The draft report focuses on an October 2008 complaint alleging that EPA's Antimicrobial Testing Program (ATP) was withholding information on product failures from intended users. This response is limited to the factual accuracy of language in the report related to enforcement.

At A Glance Cover Sheet The report concludes that the ATP is not withholding information on product failures from intended users and identifies the Office of Pesticide Programs – Antimicrobial Division (OPP-AD), the Office of Enforcement and Compliance Assurance (OECA), and applicants (manufacturers) as the intended users of the information. We suggest that OIG consider revising the draft report to reflect that hospitals, nursing homes, and other health care facilities are also intended users of information on product failures.

OIG Response: In this review, we defined intended users as those notified of product failures in OPP-AD's procedures: manufacturers, OPP, and OECA. Notification of product consumers (e.g., hospitals, nursing homes, and other health care facilities) is not addressed in OPP-AD procedures and was therefore not within our scope.

Background Section, page 1, third paragraph The draft report states, "If a product passes efficacy testing, a memo is sent to the manufacturer citing the test results." This statement requires clarification. We suggest that OIG revise this statement, as follows: "If a product passes efficacy testing, the Agency sends a letter to the manufacturer which contains a copy of the product test results of each product tested by the ATP."

OIG Response: The wording in the background section has been amended to provide greater clarity.

Background Section, page 2, second paragraph The draft report states, "For product failures of 4 or more out of 60 samples, the product is referred for an enforcement case review (enforcement action)." This statement is inaccurate. We suggest the OIG revise this statement, as follows: "For product failures of 4 or more out of 60 carriers, OPP-AD prepares a product evaluation report and an enforcement case review specifically about the product(s). OPP forwards these documents to OECA for consideration. OECA analyzes the referral package to determine whether the evidence is sufficient to support an enforcement action. If OECA determines that the referral includes sufficient evidence to bring a case, OECA forwards the file to the regional enforcement office for appropriate action."

OIG Response: We amended our description of the "60 carrier" use-dilution test for greater clarity. Our description of OECA enforcement options is unchanged as we did not review the disposition of enforcement review cases stemming from 2008 products test failures.

Should you have any questions or concerns regarding this response, please contact OECA's Audit Liaison, Gwendolyn Spriggs at 202-564-2439.

cc: Adam Kushner, OECA
Margaret Schneider, OECA
Lauren Kabler, OECA
Gwendolyn Spriggs, OECA

Appendix B

Distribution

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