U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

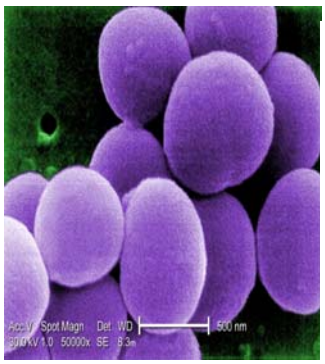
Catalyst for Improving the Environment

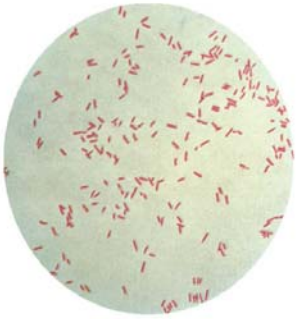
Evaluation Report

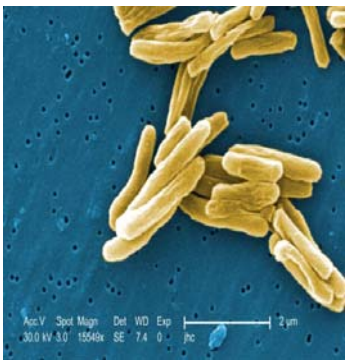
EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products

Report No. 11-P-0029

December 15, 2010







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Abbreviations

AD	Antimicrobial Division
ATP	Antimicrobial Testing Program
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	U.S. Government Accountability Office
OECA	Office of Enforcement and Compliance Assurance
OIG	Office of Inspector General
OPP	Office of Pesticide Programs
SOP	Standard Operating Procedure
SSURO	Stop Sale, Use, or Removal Order

Cover photos: *From left*: *Staphylococcus aureus* bacteria; *Pseudomonas aeruginosa* bacteria; and *Mycobacterium tuberculosis* bacteria. (Centers for Disease Control and Prevention photos)

U.S. Environmental Protection Agency
Office of Inspector General

11-P-0029
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At a Glance

Catalyst for Improving the Environment

Why We Did This Review

We initiated this review to evaluate whether U.S. Environmental Protection Agency (EPA) systems ensure that registered antimicrobial pesticide products are effective or that appropriate corrective actions are taken when products are found to be ineffective.

Background

Antimicrobial pesticides are designed to destroy or suppress harmful bacteria, viruses, and other microorganisms on inanimate objects and surfaces in hospitals and other settings. EPA's Office of Pesticide Programs initiated the Antimicrobial Testing Program (ATP) to test antimicrobial products in response to a 1990 U.S. Government Accountability Office report, which concluded that EPA lacked an enforcement strategy to ensure that registered disinfectants sold and distributed worked as claimed on product labels.

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/2011/20101215-11-P-0029.pdf

EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products

What We Found

ATP's design and implementation cannot provide assurance to the public that the product label claims are valid. ATP has been testing to ensure antimicrobial products, including hospital disinfectants and tuberculocides, meet stringent efficacy standards. However, after nearly 19 years, over 40 percent of registered products have not been tested. Those that have been tested have experienced a consistently high failure rate. During our review, EPA was requesting test sample submissions from manufacturers using a voluntary process known as the ATP "direct shipment" initiative, adopted in December 2008. However, the process is considered insufficient for enforcement actions. Also, EPA does not have a strategy for informing hospitals and other likely end-users of failed test results or when enforcement actions are taken. EPA's implementation of the ATP has not delivered on its mission. Rather than providing increased assurance that antimicrobial products are efficacious, it raises concerns regarding the integrity of EPA's product registration process. Ultimately, there may be products on the market that are ineffective.

Sometimes, the response to ATP test failures is retesting, which can take years. Meanwhile, the product may remain available for use in hospitals and the public. Testing of samples obtained through the ATP voluntary direct shipment initiative lacked appropriate chain of custody and therefore the results could not be considered adequate to support an enforcement action.

What We Recommend

We recommend that EPA redesign its process to verify antimicrobial effectiveness. The new program should have a testing program that provides reasonable efficacy assurances for all registered tuberculocides, hospital-level disinfectants, and registered sanitizers; and all subsequently registered products. Also, the program should provide an efficient sampling protocol that enables regulatory and enforcement actions as well as consistent monitoring of enforcement actions taken by EPA regions.

The Agency agreed that the program should be redesigned, and agreed with most of the findings of the draft report. The Agency did not agree with how we characterized some aspects of the program as voluntary. While the Agency did not explicitly agree with the recommendations, we found the Agency to be responsive to our recommendations.

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

THE INSPECTOR GENERAL

December 15, 2010

MEMORANDUM

SUBJECT: EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products
Report No. 11-P-0029

FROM: Arthur A. Elkins, Jr.
Inspector General

TO: Steve Owens
Assistant Administrator for Chemical Safety and Pollution Prevention

This is our report on the antimicrobial pesticide products 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 audit resolution procedures.

The estimated cost of this report, calculated by multiplying the project's staff days and expenses by the applicable daily full cost billing rates in effect at the time, is $690,128.

Action Required

In accordance with EPA Manual 2750, you are required to provide a written response to this report within 90 calendar days. You should include a corrective actions plan for agreed-upon actions, including milestone dates. Your response will be posted on the OIG's public website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal. We have no objections to the further release of this report to the public. We will post this report to our website at http://www.epa.gov/oig.

If you or your staff have any questions, please contact Wade Najjum at 202-566-0832 or najjum.wade@epa.gov, or Jeffrey Harris at 202-566-0831 or harris.jeffrey@epa.gov.

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Chapter 1
Introduction

Purpose

The objective of this evaluation was to determine whether EPA systems ensure that registered antimicrobial products are effective or that appropriate corrective actions are taken when products are found to be ineffective.

Background

Antimicrobial pesticides are designed to destroy or suppress harmful bacteria, viruses, and other microorganisms on inanimate objects and surfaces in hospitals and other settings. These pesticides are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) by EPA's Office of Pesticide Programs (OPP). EPA reviews test data submitted by manufacturers to verify that products with a public health claim are effective during the registration process.[1] The Antimicrobial Division (AD) within OPP leads the Antimicrobial Testing Program (ATP) effort and works closely with OPP's Biological and Economic Analysis Division, as well as the Office of General Counsel, the Waste and Chemical Enforcement Division in the Office of Enforcement and Compliance Assurance (OECA), and regional enforcement offices.

The ATP is a post registration efficacy testing program. According to the Agency, the intent of the ATP is to determine whether products in the marketplace are efficacious and continue to perform in a manner consistent with the product's initial registration. EPA focuses its oversight on infection control products[2]: tuberculocides and hospital-level disinfectants.[3] The ATP was initiated in response to a 1990 U.S. Government Accountability Office (GAO) report.[4] The GAO found that EPA lacked an enforcement strategy to ensure that once registered, disinfectants sold and distributed in the marketplace worked as claimed on product labels. The GAO noted that historical enforcement and other data estimated that 20 percent of disinfectants marketed did not work as claimed, posing health risks to users.

[1] Under FIFRA, the registrant of a product with a public health claim is required to submit efficacy, or effectiveness, data to EPA in support of the product's registration. EPA reviews the effectiveness data as part of the registration process for each product. If the data meet efficacy standards and all other requirements for registration are met, the product qualifies for registration and is issued a distinct identification number, or EPA registration number, that appears on the product's label along with other required statements.
[2] Sterilant testing was completed in 1993. In 1996, regulatory authority for certain liquid chemical sterilant products was transferred to the Food and Drug Administration.
[3] A hospital disinfectant must be effective against at least two microorganisms: *Staphylococcus aureus and Pseudomonas aeruginosa.* Tuberculocidal products must also be effective against *Mycobacterium bovis.*
[4] GAO/RCED-90-139, Disinfectants: EPA Lacks Assurance That They Work (1990).

Noteworthy Achievements

The AD is undertaking a "lean review" of the ATP in an effort to improve the program by increasing efficiency. The review will focus on process flow in an effort to streamline the program's processes and activities and eliminate unnecessary or redundant steps. The first meeting to initiate this review was held in June 2010.

Scope and Methodology

We performed our evaluation between October 2009 and September 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the review to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our review objectives. The evidence obtained provides a reasonable basis for our findings and conclusions based on our objectives.

To evaluate EPA's response to ATP product failures, we randomly selected a sample of 24 hospital disinfectants that failed efficacy tests from fiscal years 2004 through 2009.[5] For each sample item, we reviewed the case files and interviewed appropriate regional and headquarters staff. We interviewed staff from the AD, OECA, and EPA Regions 2, 3, 4, 5, 7, 8, and 9.

We also reviewed reports and data in support of the status of products tested and products needing to be tested. Additionally, we met with external stakeholders and laboratory staff regarding the ATP testing protocols.

Prior Audit Coverage

EPA Office of Inspector General (OIG) Report No. 09-P-0152, *Results of Hotline Complaint Review of EPA's Antimicrobial Testing Program*, was issued May 27, 2009 (www.epa.gov/oig/reports/2009/20090527-09-P-0152.pdf). In 2008, OIG received a Hotline allegation that the AD was withholding information on product failures from its intended users. The report concluded that the Hotline claim was unsubstantiated.

[5] During our sample review, we noted that one of the sample files was lost due to flooding damage at an EPA office. Only 23 samples were reviewed from our initial random sample of 24.

Chapter 2
Antimicrobial Testing Program Is Not Ensuring Efficacy of Products in the Marketplace

The ATP's design and implementation cannot provide assurance to the public that the product label claims are valid. The ATP has been conducting post registration testing to ensure products meet stringent efficacy standards. However, after nearly 19 years, over 40 percent of registered products have not been tested. Those that have been tested have experienced a consistently high failure rate. Sometimes the response to ATP test failures is retesting, which can take years. Meanwhile, the product may remain available for use in hospitals and the public. In December 2008, EPA adopted a voluntary process to acquire test samples from manufacturers, known as the ATP "direct shipment" initiative. However, testing of samples obtained through the initiative lacked appropriate chain of custody, and therefore the results could not be considered adequate to support an enforcement action. Also, EPA does not have a strategy for informing hospitals and other likely end-users when enforcement actions are taken but rather relies on the ATP website to communicate product status to potential end-users. Ultimately, there may be some products on the market that are ineffective.

EPA Has Yet to Test All Registered Antimicrobial Pesticides

The ATP has been testing antimicrobial products since 1991 with the goal to ensure that products in the marketplace meet stringent efficacy standards. As of July 22, 2010, EPA advised that it had tested 379 of 656[6] active hospital disinfectants registered by EPA for efficacy. Over 40 percent of active hospital disinfectants have yet to be tested. The AD intended to complete efficacy testing of the remaining 277 (of 656) untested registered hospital disinfectant products by the end of 2010. Furthermore, while focusing on products with the greatest public health impacts, the ATP has limited the types of products that it tests to hospital disinfectants and tuberculocides. However, sanitizers, while a public health antimicrobial product, are not currently part of ATP and therefore have not been subject to post registration efficacy testing by EPA.[7]

Starting in December 2008, the AD requested that product samples be directly shipped to AD laboratories for efficacy testing, in an effort to increase the number of products tested. The process was implemented to improve the post-market evaluations of products, promote product stewardship and efficiency, and obtain samples of all untested remaining products. Prior to December 2008, the AD

[6] AD set the universe of products to be tested as products registered as of September 30, 2009.
[7] Sanitizers are used to reduce, but not necessarily eliminate, microorganisms from the inanimate environment to levels considered safe as determined by public health codes or regulations.

relied on sample collection by official federal and state inspectors. According to OECA staff, using inspectors for sample collection was resource intensive and did not provide a great number of products being made available for testing. While this initiative did increase the number of products submitted for testing, it curtailed EPA's ability to conduct enforcement actions on failed products discussed in greater detail later in this chapter.

In December 2008, November 2009, and March 2010, the AD issued letters to primary registrants asking them to voluntarily send samples of their products to a specified EPA laboratory for testing. During our review, products were only being tested if manufactures voluntarily submitted samples for testing. Manufacturers that did respond either submitted samples to be tested, or informed EPA that their product was not currently in production.[8] Over 60 percent of the remaining untested products have not been scheduled for efficacy testing. AD staff stated that manufacturers for these products have responded to the direct shipment letters stating their products are not currently in production. According to AD, it is their practice to only test products that are currently in production. Therefore, the AD has removed these products not in production from their list of products to be tested by December 2010. While these products may not be in production, they may be available on the market.

One consequence of not having tested over 40 percent of the products is the potential presence of ineffectual products on the market for extended periods of time. During our sample review of 23 failed products, we found that the average time between product registration and product efficacy testing was 14 years.[9] The length of time between product registration and testing of efficacy potentially increases the amount of time ineffective products are available on the market and in use in hospital settings.

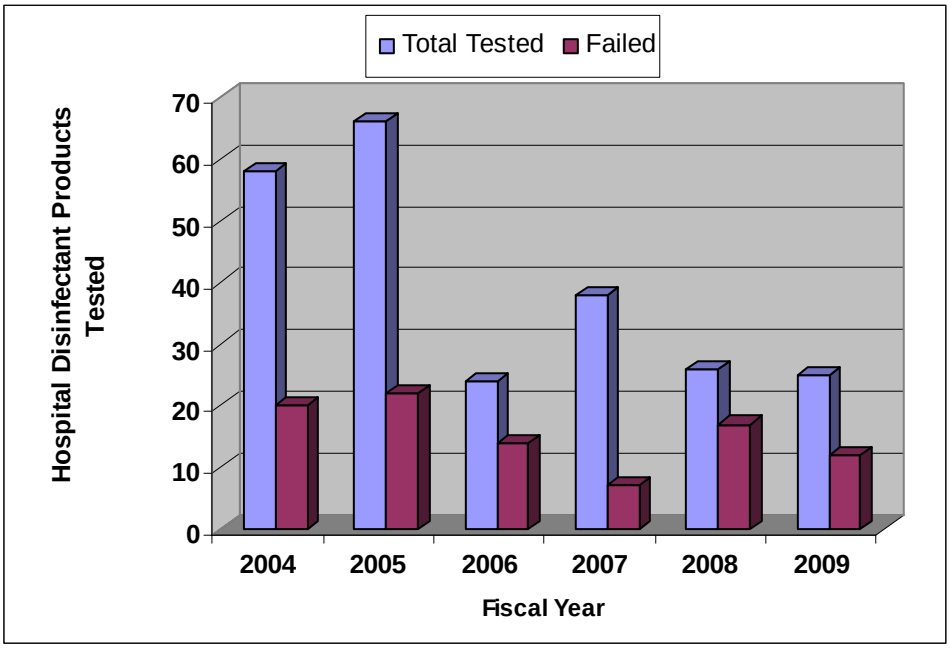
Registered Antimicrobial Pesticides Frequently Fail Efficacy Testing

Registered EPA antimicrobial pesticides fail EPA's post-registration efficacy tests at a high rate. Since 2004, on average, more than one-third of tested hospital disinfectant products have failed efficacy tests under the ATP. Figure 2-1 illustrates that the frequency of hospital disinfectant product failures has been consistently high since at least 2004. Moreover, half of products tested as tuberculocides have failed efficacy testing.

[8] Manufacturers are requested to submit samples for products that are packaged, labeled, and ready for release for shipment.

[9] This was calculated using the product registration date. However, EPA did not start testing products until 1991. Many of the products were registered and on the market for years prior to the creation of the ATP.

Figure 2-1: ATP product failure rates 2004–2009



Source: OIG based on analysis of Agency data.

EPA Actions Vary in Response to Product Failures

When registered products fail efficacy testing, EPA is responsible for ensuring actions are taken to return the product to compliance. The type of action depends on the severity of the failure.[10]

The ATP's product failure standard operating procedures (SOPs) state that if 2 or 3 tubes of growth occur, the product is referred for regulatory action. Possible actions include the manufacturer modifying the label claim, deleting the label claim, or retesting. If 4 or more failures occur, the product is to be referred to OECA for an enforcement action. Possible enforcement actions include, but are not limited to, Stop Sale, Use, or Removal Orders (SSUROs) and Civil Administrative Complaints. EPA may issue a SSURO prohibiting the person who owns, controls, or has custody of a violative pesticide or device from selling, using, or removing that product except in accordance with the provisions of the SSURO. EPA uses the FIFRA Enforcement Response Policy to determine the appropriate enforcement response and penalty amount for violations of FIFRA. EPA may issue a civil administrative complaint to any person who violates FIFRA. Complaints are usually resolved through issuance of a consent agreement and final order, which requires payment of a civil penalty and may also require correction of the violation.

[10] Severity as indicated by the number of tubes with microorganism growth out of 60 using the Use Dilution Test.

We selected a random sample of 24 products that failed efficacy testing from 2004 through 2009. Eleven of the products were addressed using regulatory actions. Under regulatory actions, the following options can be considered for resolution: label amendments, retesting of the product, reformulate the product, and product cancellation. However, we found that for five failed products for regulatory corrections, no actions have yet been taken because the manufacturers requested for their product to be retested.

ATP staff stated that once a sample of the failed product is received from the manufacturer, it will be placed in the testing queue for retesting. On average, for the five failed products in our sample, 3.8 years have passed since they had their first efficacy test. As of August 2010, products on the retest list have not been retested and are most likely still available on the market.

In contrast, we found that the 12 cases referred to OECA and the regions were addressed with some form of enforcement action. The various enforcement actions included payment of fines, voluntary recalling and stop sales of products, and product label changes. Nine of the 12 manufacturers of the failed products either voluntarily recalled their products and/or paid fines. In the course of our case reviews, we noted different regional office reactions to the same failure rates. Where some regions issued SSUROs for cases involving failed antimicrobial products, others did not. According to OECA staff, when a SSURO is issued, the manufacturer is required to provide documentation that it has met the terms and conditions of the SSURO. However, we found that limited followup is conducted to ensure compliance.

Since 2008, Enforcement Actions Curtailed by Voluntary Manufacturer Sample Submissions

Since December 2008, the direct shipment initiative has been used to obtain ATP test samples and has increased the number of products available for testing.[11] However, the initiative curtailed enforcement actions from taking place for failed products. According to the AD's SOP, if a hospital disinfectant is tested and 4 or more failures occur, the product should be referred to the regions for an enforcement action.[12] However, we found 25 of the 32 failed products received via direct shipment are being addressed by regulatory actions instead of an enforcement action. EPA deviates from its SOPs regarding testing failures of products received via direct shipment.[13] It also refrains from enforcement actions, such as issuing SSUROs and assessing fines under FIFRA statute.

[11] Only 2 of the 24 randomly tested OIG sample items were possibly submitted using the direct shipment method. Both samples were addressed using regulatory corrections instead of enforcement.
[12] Standard Operating Procedure for the Review of Product Failures in the Antimicrobial Testing Program, September 26, 2007.
[13] The AD stated that as a result of the lean process, modified SOPs will be updated and finalized by the end of the calendar year 2010.

During our review, OPP maintained that products received by direct shipment were not enforceable because they did not have a chain of custody. Chain of custody is often a point of dispute during enforcement trials for failed efficacy results. The chain of custody is important to ensure that the product sample is not potentially contaminated during transport from manufacturer site to the lab. OECA staff said that they would not be able to pursue enforcement cases for products that do not have chain of custody. According to OECA, enforcement relating to product failures associated with the voluntary direct shipment initiative samples could be compromised if sample integrity cannot be assured from the point of shipment by the registrant or producer to the receiving test laboratory or if the laboratory fails to adequately implement chain of custody procedures upon receipt of the direct-shipped samples. If the integrity of the product sample can be adequately documented, enforcement would not be compromised on the basis of chain of custody concerns. Regional staff also stated that the direct shipment letters could request products to be sent using chain of custody. However, the direct shipment request letters have not required, nor instructed how, to ensure proper chain of custody.[14]

According to the Agency during voluntary direct shipment initiative, they retained its ability to collect products during inspections and therefore could utilize regulatory and/or enforcement actions where appropriate. AD staff stated that if a product has "egregious" test failures, or those with 10 or more tubes of growth, the product would be obtained via the traditional sample collection process and retested later. This process would require a state or regional inspector to physically obtain the samples to ensure chain of custody. However according to OECA, although regions were available during FY2010 to collect ATP samples upon request, no such on-site sample collections occurred during the period from October 1, 2009 through September 30, 2010.[15] As a result no enforcement actions were taken during that period.

EPA Relies on the ATP Website to Notify Hospitals and Public Health Users of Product Failures or Enforcement Actions

EPA does not have a communications strategy for informing end-users[16] of antimicrobial test results or enforcement actions but relies on the ATP website to communicate product information. Because EPA does not conduct pre-registration testing, independent verification testing performed by ATP may be the public's only validation of label claims. EPA's verification of compliance is through the ATP. While EPA has conducted outreach to healthcare associations to

[14] As stated in the Agency's response to the draft report, EPA has taken the first steps to develop additional procedures to strengthen chain of custody and further facilitate the pursuit of enforcement actions in the future for direct shipment of products.

[15] According to the Agency's response to the draft report, beginning in the first quarter of FY 2011, EPA will be resuming collection of samples through inspections.

[16] In addition to hospitals, other establishments such as beauty and tanning salons, small clinics, veterinaries, and nursing homes are potential end-users of antimicrobial pesticide products.

learn about their use of hospital disinfectants and to discuss the Agency's registration and review of products, including the ATP, current procedures only require that the AD notify OECA and the manufacturer when a product fails. The AD is not required to notify the general public. OECA and regional offices conducting enforcement actions have the discretion to notify the public of actions related to product failures. A notification can consist of a press release describing EPA enforcement actions taken to address noncompliant antimicrobial products. However, we found that some regions do not issue press releases for cases related to failed antimicrobial products. Enforcement actions have implications for users nationwide but may be publicized only within a single region or not at all. According to AD, EPA relies on the website to inform end users of product failures.[17] However while the website provides information regarding product status, the website does not clearly identify products that are considered ineffective.[18]

Conclusions

As currently executed, the ATP does not ensure that hospital disinfectants and tuberculocides in the marketplace meet efficacy standards. Although approximately 60% of the products have undergone post-registration efficacy testing by EPA, more still needs to be done. Many products have yet to be tested, and of those that have been tested, failure rates are high. Additionally, sanitizers, while a public health antimicrobial product, are not currently part of ATP and have not been subject to efficacy testing by EPA. Neither the design of the program nor its implementation assures the public that the manufacturer's public health claims on the label are valid. Additionally, test results of samples that are submitted via the direct shipment initiative were not considered sufficient for enforcement. Due to the fact that each region has its own communication policy and there is no national requirement for issuing enforcement case press releases, enforcement actions, when taken, are not always communicated to end-users. The AD's implementation of the ATP has not delivered on its mission. Rather than providing increased assurance that antimicrobial products are efficacious, the ATP's program value and the continued high failure rate of products raises concerns regarding the integrity of EPA's product registration process.

[17] In June 2009, EPA developed a web page on the testing status of registered hospital disinfectant products.
[18] The ATP web page was updated in October 2010, subsequent to our draft report issuance, to provide the public with information regarding the total number of registered hospital disinfectant products, which products have been tested, and those that are in compliance.

Recommendation

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention:

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

   (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.
   (b) An efficient sampling protocol that enables regulatory and enforcement actions as appropriate.
   (c) Consistent implementation, communication, and followup of enforcement actions by EPA regions.
   (d) A testing program to provide reasonable assurance of the efficacy of registered sanitizers.

Agency Comments and OIG Evaluation

The Agency agreed that the program should be redesigned, and agreed with most of the findings of the draft report. The Agency also provided technical corrections. Based on our analysis of the Agency's comments we made appropriate corrections. The Agency did not agree with how we characterized some aspects of the program as voluntary and the implications of the direct shipment on the Agency's ability to conduct enforcement actions. We believe we accurately reflect the nature of the voluntary direct shipment initiative that was in place during the course of our evaluation. Furthermore, based on the Agency comments, EPA has taken first steps to address chain of custody issues with the direct shipment initiative to further facilitate the pursuit of enforcement actions in the future for direct shipment of products.

While the Agency did not explicitly agree with the recommendations, we found the Agency to be responsive to our recommendations. These recommendations remain open pending agreed-to corrective actions. We look forward to the Agency's response to the final report, which should include a corrective action plan for all agreed-upon actions and milestone dates for accomplishing each of those actions.

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
1	9	Redesign the process used to verify antimicrobial effectiveness. Specifically, we recommend a new program design that includes: (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. (b) An efficient sampling protocol that enables regulatory and enforcement actions as appropriate. (c) Consistent implementation, communication, and followup of enforcement actions by EPA regions. (d) A testing program to provide reasonable assurance of the efficacy of registered sanitizers.	O	Assistant Administrator for Chemical Safety and Pollution Prevention			

[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

Agency Response

The response from the Assistant Administrator was signed on October 26, 2010 and received on November 1, 2010.

MEMORANDUM

SUBJECT: Comments on OIG's Draft Evaluation Report "EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products" (September 24, 2010/Project No. OPE-09-0020)

FROM: Stephen A. Owens
Assistant Administrator

TO: Arthur A. Elkins, Jr.
Inspector General

This memorandum is in response to the Office of Inspector General's (OIG) Draft Evaluation Report, entitled *EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products* ("Draft Report"), which evaluated the Agency's Antimicrobial Testing Program (ATP). The Agency thanks the OIG for this opportunity to comment on the Draft Report and offers the following comments to clarify characterizations of the ATP for the Final Report.

The Agency agrees with the OIG that the program should be redesigned and with most of the findings of the Draft Report. The ATP program is critical to EPA's mission of protecting human health and the environment, and EPA is actively working to improve this program. It is important to note, however, that the ATP is not a voluntary program, nor is it a stand-alone program. We want to assure you that the process to register disinfectants making a public health claim, including products for use in hospitals and healthcare settings, is rigorous. Registrants conduct efficacy tests according to the Agency's product performance guidelines, using the methods that are outlined in those guidelines. A product is registered only after the Agency determines that submitted efficacy data support a finding of product efficacy, and the product meets other applicable requirements. The ATP complements the registration process by determining through laboratory evaluations whether hospital disinfectants and tuberculocides meet the Agency's efficacy standards once they are registered and in the marketplace.

Over the past two years, the Agency has been communicating on a regular basis with healthcare associations, whose members are the front-line purchasers and users of the hospital disinfectant products. We inform them about the efficacy of hospital disinfectants, including the products that fail testing. In fact, the ATP and the issue of failing products were discussed at the annual meetings of two healthcare associations this year. The associations have informed the Agency that antimicrobial disinfectants are one part of comprehensive infection control

programs in hospitals and other healthcare settings. Other important factors in preventing the spread of infections in healthcare settings, such as how often and how thoroughly the healthcare staff wash their hands, are also critical. Disinfection of hard surfaces is an important practice, but it is only one component of a larger program to control the spread of infection in healthcare settings.

Although there remain products that are currently registered as hospital disinfectants and that have not been tested, the Agency believes that the majority of the products actually being used in hospitals and healthcare institutions have, in fact, been tested under the ATP. EPA has attempted to collect each of the products currently registered under the ATP. As discussed below, some of these products are not, and have not been for some time, in production. Generally, those products being produced and marketed were available for collection, have been collected, and have been tested.

EPA Has Efforts Underway to Improve the Effectiveness of the ATP

The Office of Pesticide Programs (OPP) has undertaken a management effectiveness review, called the "LEAN Review of the ATP," to increase the efficiency and effectiveness of product collection, testing, and the resolution of product failures. EPA appreciates that the OIG's Draft Report highlights the LEAN Review as a noteworthy achievement and states that the LEAN Review is off to a positive start. As a result of the LEAN Review and the reestablishment of regular communication on ATP issues across the Agency, EPA has taken the first steps toward developing a more streamlined and effective program including:

- Clarifying the roles and responsibilities of Agency programs and staff to eliminate redundancies and to shorten the time to test products and act upon results.

- Revising Standard Operating Procedures (SOPs) for the collection of sample products by the EPA regional offices to ensure consistency. The list of targeted samples includes all remaining products originally requested under the direct shipment program that are in production but have not yet been sent in by the registrants for testing. The products will be collected to ensure they are tested or in the queue for testing by December 31, 2010.

- Establishing a database to better track milestones for products from the time of receipt by the lab, through testing and resolution of any testing failures.

- Developing amendments to the letter sent to pesticide registrants concerning antimicrobial product testing failure, to include both regulatory and enforcement actions and stringent timeframes for response.

- Developing additional chain of custody procedures that instruct registrants about how to ship in a manner that adheres to chain of custody requirements and in a manner that can be documented. These procedures will be incorporated into the direct shipment letters. Changes in receipt and handling of the direct shipments at the labs will also be included in the procedures and will serve to strengthen chain of custody and further facilitate the pursuit of enforcement actions in the future for direct shipment of products.

In addition to these efforts, EPA has established intra-Agency teams to examine the long-term structure of the program. These teams are charged with the following:

- Reviewing the method in which failures were handled in the past and how they should be handled today and in the future. This includes both chemistry and efficacy failures.
- Establishing specific timelines for handling failures, such as setting timeframes for failure letters, as noted above.
- Charting a new course for the ATP program. Developing recommendations for new paradigms for product registration, including examining options for mandating a new testing paradigm.
- Determining the appropriate steps to ensure that sanitizer products are efficacious.

Registration of Antimicrobials

It is important to recognize that the ATP is one part of a larger regulatory framework for pesticides. EPA registers all antimicrobial products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA requires companies seeking to register public health antimicrobial pesticides, including hospital disinfectants and tuberculocides, to ensure the effectiveness of their products before the products are registered. Companies are required to submit efficacy data demonstrating the effectiveness of those kinds of products against specific microorganisms. Companies conduct efficacy testing according to the Agency's product performance guidelines, using the methods that are outlined in those guidelines. The Agency uses efficacy test data to substantiate and determine the adequacy of product use directions and label claims of efficacy. Once the label is approved and the product is registered, it may enter the marketplace.

The intent of the ATP is to determine whether products in the marketplace are efficacious and continue to perform in a manner consistent with the product's initial registration. Post-registration testing under the ATP is conducted using the same Agency-approved testing methodologies by which the products were registered.

ATP Is Not a Voluntary Program

It is important to recognize that the ATP is not a voluntary program, as the Draft Report suggests. In 2009, the Agency instituted an interim voluntary direct shipment program as a one-time effort to collect previously unavailable products for testing. The Agency retains its ability to collect products during inspections and to utilize regulatory and/or enforcement actions where appropriate. Under the interim voluntary direct shipment program, samples were sent to the laboratory directly by companies in response to a request by the Agency and the chain of custody was not retained in some instances. Beginning in the first quarter of FY 2011, EPA is resuming collection of samples through inspections. An inspector will be sent to collect an official chain of custody sample from each company that failed to respond to the Agency letters requesting them to submit a product for testing under the direct shipment program. If testing indicates that the product does not meet the efficacy standards, the Agency will pursue enforcement and/or regulatory action as appropriate.

The Draft Report mistakenly indicates that the voluntary direct shipment initiative has completely eliminated enforcement for failed products, and recommends that the program be redesigned to establish a sampling protocol that enables enforcement, and that enforcement actions should be implemented and communicated consistently by EPA regions. While the ATP direct shipment program was initially focused on a regulatory resolution scheme for failed products, EPA is establishing revised sampling protocols to ensure that future samples will be collected in a manner that will facilitate enforcement when samples fail testing. These protocols will help to ensure consistency in how regions will follow-up on failed samples.

In addition, in December 2009, the Office of Enforcement and Compliance Assurance (OECA) revised its Federal Insecticide, Fungicide, and Rodenticide Act Enforcement Response Policy (FIFRA ERP). The FIFRA ERP is used to ensure national consistency in enforcement actions and is used as a guide by headquarters and the regions in considering the facts and circumstances of each case. The ERP prescribes a range of enforcement options, which include the issuance of a Notice of Warning (NOW), a civil administrative complaint, or a Stop Sale, Use, or Removal Order (SSURO), depending upon the facts and circumstances of each violative action and establishes a consistent standard for determining when each enforcement option should be used. NOWs are used to address relatively minor and easily corrected violations. More serious violations are usually addressed through civil administrative complaints and are usually resolved through issuance of a consent agreement and final order which requires payment of a civil penalty and may also require correction of the violation. SSUROs are used to prohibit violative pesticide products or devices from being sold, used, or removed except in accordance with the provisions of the SSURO.

Clarification of Actions Taken When a Product Fails under the ATP

Under the ATP, a product passes efficacy testing if no more than one out of 60 tubes shows growth of the test organism. Under this scenario, the Agency notifies the company manufacturing the product that its product has passed efficacy testing.

If 2 or 3 tubes of growth of the test organism occur, the company is notified. The company then has the option of retesting its product, amending the label to delete the claim, or voluntarily cancelling its product. If retesting is conducted and the product passes, the Agency will review the data and, if found acceptable, no further testing under the ATP will be conducted. The product will be deemed to be in compliance and the company will be notified. If the company's testing results in 2 or 3 tubes of growth of the test organism, actions consistent with those described below for 4 or more positive tubes will be considered.

If 4 or more tubes of growth of the test organism occur, the registrant must take corrective action, and regulatory and/or enforcement actions may be taken. Specifically, the registrant may voluntarily cancel the product, or revise the label to request removal of the organism(s) for which it is ineffective, along with all references for use of the product in healthcare settings. Alternatively, the registrant may modify the label directions (e.g., increase the contact time from 5 minutes to 10 minutes) or reformulate the product. If either of these latter options is pursued, the product must be retested by the company and the data submitted to the Agency for review. If the Agency determines that these data demonstrate that the product is

now efficacious, the Agency will confirm the company's findings by retesting the product under the ATP.

EPA Targets the Most Critical Products for ATP Testing

As the Draft Report notes, a number of products were not in production when the registrant received the direct shipment letter. The Agency agrees with the OIG that expeditious testing of products currently being sold and used in hospitals is a priority. However, there are various "not in production" scenarios that result in different likelihoods (or not) of a product being in the current channels of trade. In some business models, one product may be manufactured to meet current or anticipated demand, and then the production line may switch to another formula due to different demand. Because it takes approximately 18 months for products to move through the channels of trade, it is likely that recently produced products are still available in the marketplace. On the other hand, products for which no production has occurred for a number of years are unlikely to be available in the marketplace. This scenario occurs because under FIFRA, registrants are permitted to maintain a registration without producing a product as long as the company pays an annual maintenance fee.

As mentioned previously in this memorandum, in 2009, the Agency requested ATP samples be sent in voluntarily by registrants. As a result, registrants declared 143 products to be "not in production." EPA then researched production data for these 143 products and found that 114 of them had not been produced since 2007. Subsequently, EPA conducted an internet search and learned that only about 5% of the 143 products were available in the marketplace. Although the number of these purported "not in production" products available on the marketplace is small, EPA intends to conduct a rigorous assessment of the status of each product and have inspectors collect available products.

To further ensure that the Agency targets the most critical products in the ATP, we are exploring the use of hospital product purchase data to prioritize sample collection and testing. This information would also help the Agency alert hospitals about product failures.

EPA Works to Communicate Product Failures

EPA has worked hard to communicate product failures to the public. Since 2008, OPP has conducted outreach to healthcare associations to learn about their use of hospital disinfectants and to discuss the Agency's registration and review of products, including the ATP. The Agency has also stressed to industry and many user groups the importance that these products play in protecting public health. In June 2009, the Agency developed a webpage on the testing status of registered hospital disinfectant products. On October 15, 2010, OPP updated, expanded, and improved the website as a part of the LEAN Review. The revised webpage has information on the status of registered hospital disinfectant products, indicating products meeting efficacy standards; products not meeting efficacy standards; and products under Agency (regulatory and enforcement) review. Healthcare facilities can access the webpage for help in making product purchasing and use decisions.

Recently, the Association for the Healthcare Environment (AHE) (formerly called the American Society for Healthcare Environmental Services) and the Centers for Disease Control

and Prevention (CDC) agreed to add links to EPA's ATP webpage to their websites, which will broaden the audience for this important product efficacy information and provide greater visibility to the user community. In addition, OPP, OECA, and the regions will continue partnering on communications. For example, Region 1 has an active hospital communication program that includes quarterly bulletins, list-serve notices, and an informative website. EPA will send ATP updates to end users through this network, in addition to expanding the program to other regions.

Thank you again for the opportunity to comment on the Draft Report. I hope that my clarifications of EPA positions and facts are helpful as you complete the final report. We will continue our work to realign the ATP and will develop corrective actions based on the final report. If you have questions, do not hesitate to contact me or Marty Monell, Deputy Director of the Office of Pesticide Programs, at (703) 305-7090.

Appendix B

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