U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Chemical Safety

EPA Needs a Risk-Based Strategy to Assure Continued Effectiveness of Hospital-Level Disinfectants

Report No. 16-P-0316 **September 19, 2016**

This is one of the U.S. Environmental Protection Agency Office of Inspector General's products associated with antimicrobial testing and disinfectants. For details on other reports in this area, go to:

- ***Results of Hotline Complaint Review of EPA's Antimicrobial Testing Program*** **(09-P-0152, issued May 27, 2009)**
- ***EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products*** **(11-P-0029, issued December 15, 2010)**
- ***Quick Reaction Report: Complete and Clear Information on the Effectiveness of Ebola Disinfectants Will Better Inform the Public*** **(15-P-0064, issued January 21, 2015)**

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Abbreviations

ATP	Antimicrobial Testing Program
C. diff	Clostridium difficile
CDC	Centers for Disease Control and Prevention
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	U.S. Government Accountability Office
OIG	Office of Inspector General
TB	Mycobacterium tuberculosis (M. tuberculosis)

Cover photos: Cleaning supplies (left) and a hospital room (right). (Centers for Disease Control and Prevention and California Department of Public Health photos).

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U.S. Environmental Protection Agency
Office of Inspector General

16-P-0316
September 19, 2016

At a Glance

Why We Did This Review

We conducted this review of the U.S. Environmental Protection Agency's (EPA's) Antimicrobial Testing Program (ATP) to determine whether the program ensures the efficacy of EPA-registered hospital sterilants, disinfectants and tuberculocides ("hospital-level disinfectants"); and to evaluate options for improving the ATP.

Antimicrobial pesticides are designed to destroy or suppress harmful bacteria, viruses and other microorganisms on inanimate objects and surfaces in hospitals and other settings. The EPA has a testing program— the ATP—whose purpose is to ensure that EPA-approved hospital disinfectants and tuberculocides in the marketplace continue to meet stringent efficacy standards. Products found to be effective are reported to the public on an EPA website, and those that do not meet the ATP efficacy standards need to be brought into compliance.

This report addresses the following EPA goal or cross-agency strategy:

- *Ensuring the safety of chemicals and preventing pollution.*

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EPA Needs a Risk-Based Strategy to Assure Continued Effectiveness of Hospital-Level Disinfectants

What We Found

As currently designed and implemented, the EPA's ATP does not assure that hospital-level disinfectant products continue to be effective after they are registered. Infrequent testing and reliance on voluntary manufacturer participation reduce program effectiveness. Specifically, we found:

EPA-registered hospital disinfectants help suppress microbes that cause thousands of serious illnesses every year. The EPA needs to ensure the continued efficacy of these registered products in the marketplace to protect public health.

- Once the EPA tests a product and it passes, it is listed as *Agency Confirmed Efficacy* on the agency's website and is typically not tested again; the long-term efficacy of the product cannot be assured.
- The EPA relies on manufacturers to voluntarily submit product samples for testing. In the last 3 years, out of the approximately 300 registered hospital disinfectant products that have not been tested, manufacturers submitted only 12 samples to EPA for ATP efficacy testing.

The current ATP design does not consider risk factors when prioritizing and selecting which antimicrobial products to test, and some of the microorganisms of greatest concern do not fall within the ATP's current scope.

The EPA is currently re-registering all antimicrobial products and, thereby, recertifying the efficacy of all registered products. This one-time review of registered antimicrobial pesticides is a comprehensive review that includes a review of efficacy. The EPA anticipates the re-registration of antimicrobial pesticide products to be completed by fiscal year 2021. The EPA testing conducted by the ATP is redundant in the short term while the EPA is also re-registering antimicrobial pesticides. However, following this one-time re-registration review, the EPA needs to have a risk based strategy in place that assures continued efficacy of public health products, and deters and detects noncompliance.

Recommendations and Planned Agency Corrective Actions

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention suspend administering the ATP until completion of the one-time re-registration process, and then develop and implement a risk-based testing strategy. At a minimum, the antimicrobial testing strategy should include a framework for periodic testing, define program scope, identify risk factors and methods for selecting products to test, and designate a date to commence risk-based post-registration testing. The EPA agreed with our recommendations and proposed acceptable corrective actions. All recommendations are resolved and open pending completion.

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

THE INSPECTOR GENERAL

September 19, 2016

MEMORANDUM

SUBJECT: EPA Needs a Risk-Based Strategy to Assure Continued Effectiveness of Hospital-Level Disinfectants
Report No. 16-P-0316

FROM: Arthur A. Elkins Jr.

TO: Jim Jones, Assistant Administrator
Office of Chemical Safety and Pollution Prevention

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). The project number for this evaluation was OPE-FY16-0001. 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 EPA office having primary responsibility for the issues evaluated in this report is the Office of Chemical Safety and Pollution Prevention's Office of Pesticide Programs.

Action Required

In accordance with EPA Manual 2750, your office provided planned corrective actions in response to the OIG recommendations. All recommendations are considered resolved. You are not required to provide a written response to this final report because you provided agreed-to corrective actions and a planned completion date for the report recommendations. The OIG may make periodic inquiries on your progress in implementing these corrective actions. Please update the EPA's Management Audit Tracking System as you complete planned corrective actions. Should you choose to provide a final response, we will post your response on the OIG's public website, along with our memorandum commenting on your response. You should provide your response 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 along with corresponding justification.

We will post this report to our website at www.epa.gov/oig.

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Chapter 1
Introduction

Purpose

We conducted this review of the U.S. Environmental Protection Agency's (EPA's) Antimicrobial Testing Program (ATP) to determine whether the program ensures the efficacy of EPA-registered hospital sterilants, disinfectants and tuberculocides; and to evaluate options for improving the program.

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. All pesticides—including antimicrobials—sold and distributed in the United States are regulated and registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) [1] by the EPA's Office of Pesticide Programs. The EPA must ensure that pesticides registered for use in the United States will not have unreasonable adverse effects on humans and the environment. The registration process is a scientific, legal and administrative procedure through which the EPA examines data submitted by registrants to identify the ingredients of the pesticide; and determine potential risks and benefits associated with the proposed use sites, application rates, use frequency and timing, and storage and disposal practices. As illustrated in Figure 1, as part of the registration process, the EPA evaluates potential human health and environmental effects associated with use of the product. FIFRA also requires pesticide manufacturers to consistently formulate a pesticide based on the initial registration.

Although antimicrobial pesticides are subject to the same basic regulatory provisions of FIFRA as are other pesticides, antimicrobial pesticides are subject to additional registration requirements. For example, registrants must conduct efficacy tests according to the agency's product performance guidelines, using the methods outlined in those guidelines.

[1] FIFRA, 7 U.S.C. § 136 et seq.

Figure 1: Elements of EPA's pesticide registration process

Source: EPA OIG.

Antimicrobial pesticide products are categorized as either "public health" or "non-public health," depending on the specific claims made on each product's label. Public health antimicrobial pesticides are regulated more stringently than other pesticides because serious consequences could arise from use of ineffective antimicrobials in medical settings. During the registration process for public health antimicrobials, the EPA reviews the efficacy test data submitted by manufacturers to verify that products with a public health claim are effective. According to the EPA, a public health antimicrobial pesticide product is registered only after the agency determines that submitted efficacy data support a finding of product efficacy, and the product meets all other applicable requirements.

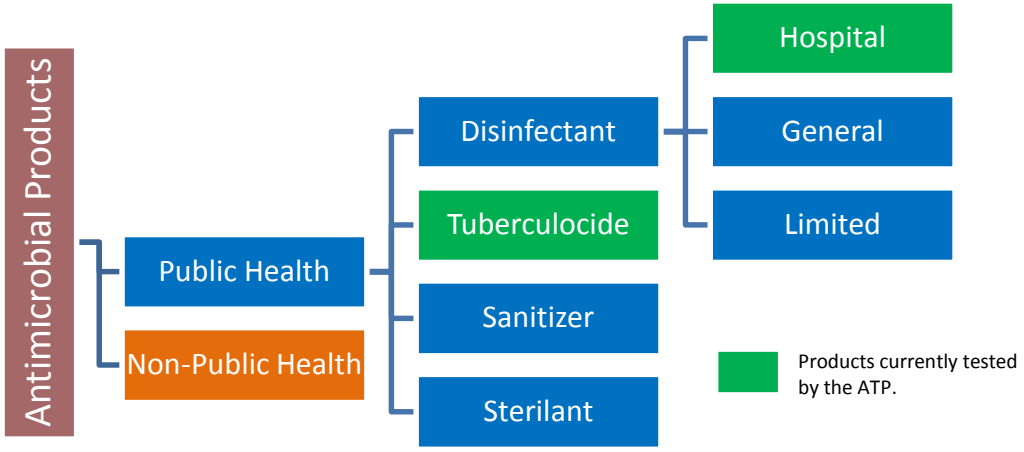
Importance of Public Health Antimicrobials

Antimicrobial disinfectants are one part of a comprehensive infection control program in hospitals and other healthcare settings. Disinfection of hard surfaces is only one component of a larger program to control the spread of infection in healthcare settings. According to the EPA, other important factors in preventing the spread of infections in healthcare settings, such as how often and thoroughly the healthcare staff wash their hands, are also critical.

Unlike other pesticides where results are usually observable, an end-user of antimicrobial products cannot visually verify that the product is effective. Due to the public health implications and the fact that users cannot readily know whether the products actually kill the germs as claimed, it is imperative that antimicrobial pesticides used in hospital settings are effective.

As illustrated in Figure 2, there are various types of public health antimicrobials. Through the ATP, the EPA currently focuses its post-registration oversight on infection control products: hospital-level disinfectants and tuberculocides. Sanitizers are not tested under the ATP, and sterilant testing was completed in 1993. Subsequently, in 1996, regulatory authority for certain liquid chemical sterilant products was transferred to the Food and Drug Administration.

Figure 2: Antimicrobial pesticides classifications



Source: EPA OIG.

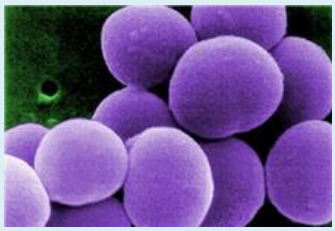
As depicted in Figure 2, disinfectants can be registered as hospital, general or limited. According to the ATP website, as of July 2016, there were over 600 EPA registered hospital disinfectants. To be considered as a hospital disinfectant, the product must be effective against at least two microorganisms: *Staphylococcus aureus* and *Pseudomonas aeruginosa.* Details on these microorganisms follow.

Risks for *Pseudomonas aeruginosa* and *Staphylococcus aureus*

Risks for *Pseudomonas aeruginosa* infection

According to the Centers for Disease Control and Prevention (CDC), patients in hospitals—especially those on breathing machines, with devices such as catheters, and with wounds from surgery or burns—are potentially at risk for serious, life-threatening infections.

Pseudomonas aeruginosa bacteria. (CDC photo)



Staphylococcus aureus bacteria. (CDC photo)

Risks for *Staphylococcus aureus* infection

According to the CDC, anyone can develop a staph infection, although certain groups of people are at greater risk, including people with chronic conditions such as diabetes, cancer, vascular disease, eczema and lung disease. In a healthcare setting, the risk of a more serious staph infection is higher because patients often have weakened immune systems, have undergone procedures such as surgery, or have intravenous catheters.

Additionally, the EPA conducts post registration testing of tuberculocide antimicrobial products. Tuberculocide antimicrobial products must be effective against *Mycobacterium bovis* BCG, which according to EPA is a surrogate organism closely related to *Mycobacterium tuberculosis*.

Risks for *Mycobacterium tuberculosis* (*M. tuberculosis* [TB])

Risks for TB infection

According to the CDC, transmission of TB is a recognized risk to patients and healthcare personnel. Transmission of *M. tuberculosis* in healthcare settings has been associated with close contact with persons who have infectious TB, particularly during the performance of cough-inducing procedures such as bronchoscopy and sputum induction. TB can also spread through the air and travel long distances.

Mycobacterium tuberculosis bacteria. (CDC photo)

The ATP is intended to complement the registration process by determining, through laboratory evaluations, whether hospital disinfectants and tuberculocides are formulated correctly and continue to meet the agency's efficacy standards once the products are in the marketplace. Under the ATP, samples of EPA-registered hospital disinfectant and tuberculocide products are tested, and a list of products found to be effective are reported to potential end users and the public

via the EPA website, on the ATP web page. Products that do not meet the ATP standards are subsequently brought into compliance through regulatory or enforcement measures.

Responsible Office

The EPA office having primary responsibility for the efficacy testing of antimicrobial pesticides is the Office of Chemical Safety and Pollution Prevention's Office of Pesticide Programs.

Scope and Methodology

We conducted our work from September 2015 through July 2016. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In support of the objectives, we reviewed relevant guidance documents, testing standards, and the FIFRA. We also reviewed reports and data in support of the status of products tested and products needing to be tested. We interviewed staff involved in administering the ATP from the Office of Pesticide Programs' Antimicrobial Division and the Biological and Economic Analysis Division. We also interviewed a staff member in the Office of Enforcement and Compliance Assurance. Additionally, we met with external stakeholders and staff from the CDC. Further, to answer the objective of determining which option is the most beneficial for improving the EPA's ATP, we reviewed the existing testing program and evaluated the proposed options.

Details on our scope and methodology, including prior reports on this subject, are in Appendix A.

Chapter 2
EPA Needs a Risk-Based Strategy for ATP to Assure Continued Effectiveness

The ATP is intended to ensure that EPA-approved hospital disinfectants and tuberculocides in the marketplace continue to meet stringent efficacy standards. However, as currently designed and conducted, the ATP does not assure that hospital disinfectant products continue to be effective after they are registered. Infrequent testing, as well as a reliance on voluntary manufacturer sample submissions, reduces the program's effectiveness. The agency's ongoing one-time re-registration of antimicrobial products, including hospital-level disinfectants, will recertify the efficacy of all registered products in the marketplace. However, upon completion of the re-registration process, the agency needs to design a risk-based testing strategy that assures efficacy, and deters and detects noncompliance, to ensure that hospital-level disinfectants continue to work as labelled to protect public health.

ATP Design Not Ensuring Efficacy of Hospital-Level Disinfectants

Program Design Does Not Ensure Continued Efficacy

The ATP is not administered in a way that assures products continue to meet efficacy standards. Once the EPA tests a product and it passes, the product is listed as *Agency Confirmed Efficacy* on the agency's website, and typically is not tested again. While this one-time test does determine the efficacy of the product at the time of testing, it cannot assure that any product on the effective list *continues* to be effective. Even though FIFRA requires pesticide registrants to consistently formulate a pesticide based on the initial registration, a risk exists that the formulation could change, rendering the product less effective or ineffective. According to the EPA, some possible causes of a formulation change include:

- Inconsistencies in distributor products.[2]
- Product degradation over time.[3]
- Production facility problems (e.g., improper quality assurance).

Since the EPA only tests products once, there could be products listed as effective on the agency's website that were tested several years ago but could now be ineffective, due to the reasons cited above.

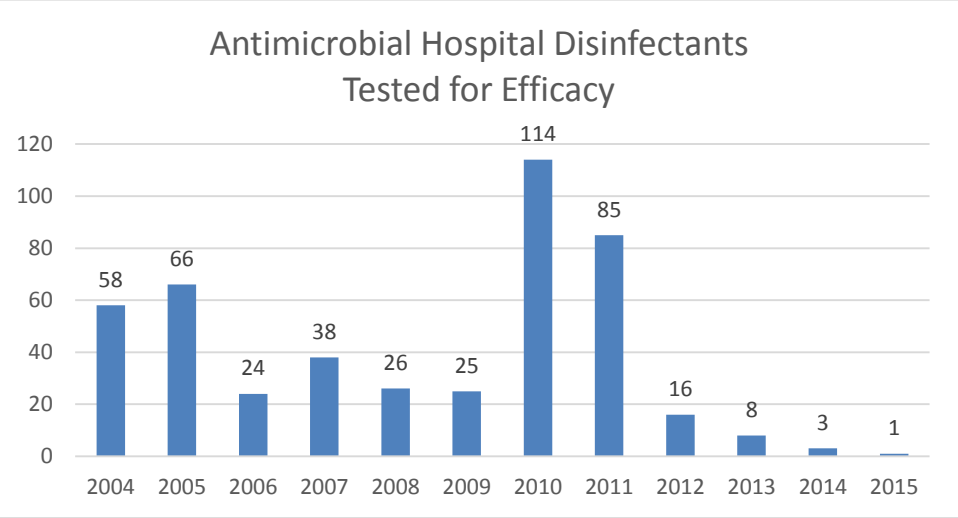
[2] Each primary product may support tens and sometimes hundreds of "supplemental distributor" products. According to the EPA, these products, which are sold by other companies, must be identical in both claim and formulation with the primary product. However, inconsistencies in distributor products could occur. EPA staff added that primary registrants are responsible for ensuring that supplemental distributors sell products that have identical formulations and claims to the parent product.

[3] Storage stability data (1 year) is required for all products during the initial registration.

Problems With Collecting Samples for ATP Testing

The number of ATP tests conducted, and the source of test samples, has fluctuated over the course of the program. Prior to 2008, the EPA relied on sample collection by federal and state inspectors. In December 2008, the agency instituted a direct-shipment initiative whereby the EPA requested manufacturers to voluntarily ship product samples to the EPA for efficacy testing. This change allowed the EPA to increase the number of samples received, and the number of tests conducted in 2010 and 2011. While this voluntary direct-shipment initiative did increase the number of products submitted for testing, it curtailed the EPA's ability to conduct enforcement actions on failed products, due to chain of custody concerns. As depicted in Figure 3, after a surge of testing in 2010 and 2011, voluntary submissions to the ATP fell sharply. According to the agency, it did not actively request sample submissions while waiting for the anticipated improvements to the efficacy testing method.[4]

Figure 3: Antimicrobial hospital disinfectants tested for efficacy, 2004–2015



Source: OIG analysis of EPA data.

While the EPA has continued to rely on the voluntary submission by manufacturers of product samples for testing, this method of collection has presented challenges. Of more than 300 untested registered hospital disinfectant products, only 12 were tested for efficacy by the ATP in the last 3 years. According to ATP staff, not all registrants were willing to submit samples, and the ATP staff also had concerns that some registrants could create "special" batches for testing. ATP staff added that some of the 300 untested products, while registered, are currently not in production. Lastly, as sample submission was

[4] In November 2013, the agency adopted the most recently revised Use-Dilution Method published by the Association of Official Analytical Chemists International, an international non-profit scientific organization that develops microbiological and chemical standards and analytical methods.

voluntary, the ATP staff said they could not anticipate when samples would be received, creating work-load challenges.

Currently, registrants of hospital disinfectants in liquid form have the option of voluntarily submitting data for their products that were tested using the 2013 version of the Use-Dilution Method for Testing Disinfectants.[5]

Antimicrobial Re-Registration Temporarily Makes ATP Redundant

The EPA initiated the one-time re-registration of antimicrobial pesticide products, which included products with public health-related efficacy claims, in part, to ensure the products are supported by acceptable efficacy data. Re-registration includes a data request to registrants for efficacy test data. If acceptable data are not received, the EPA can take those products off the market. Because of advances in scientific knowledge, the law requires that pesticides first registered years ago be re-registered to ensure they meet current scientific and regulatory standards. This one-time re-registration process requires registrants to submit efficacy data using the new test method, or ensure that the data submitted previously complies with the current standards and guidance.[6] The EPA anticipates the re-registration of antimicrobial pesticide products to be completed by fiscal year 2021.

Re-registration of Antimicrobials Pesticides

The re-registration process was authorized by the 1988 amendments to FIFRA. Re-registration is a one-time re-evaluation of pesticides first registered before November 1984. In evaluating pesticides for re-registration, the EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The agency imposes any regulatory controls needed to effectively manage each pesticide's risks. The EPA then re-registers pesticides that can be used without posing undue hazards to human health or the environment.

It is redundant for the EPA to be testing antimicrobial hospital-level disinfectants for continued post-registration efficacy while these products are also being re-registered by the EPA. The re-registration of antimicrobial pesticide products is a more comprehensive approach to ensure product efficacy, rather than only testing a few products a year under the ATP. According to Office of Pesticide Programs staff, the re-registration process will increase the level of confidence in the efficacy of registered hospital-level disinfectant products. However, following this one-time re-registration of antimicrobial pesticides, the EPA needs

[5] This option is not available for other formulation types, such as spray and towelette products, or for products with claims against Mycobacterium.

[6] According to the agency's July 2015 Efficacy Testing Standards for Product Data Call-In Responses, registrants must comply with the testing standards found in the agency's current 810 series, Product Performance Test Guidelines, published in 2012. These guidelines identify the efficacy data needed to support re-registration based on the product-specific efficacy claims. This includes data on the organisms needed to support general efficacy label claims (e.g., disinfectant, sanitizer, etc.); as well as any additional bacterial, viral and fungal organisms on the product label.

to have a testing program in place to ensure that registered public health antimicrobial products continue to be effective once on the market.

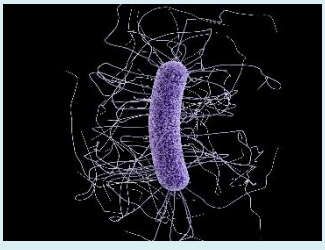
Future Program Design Should Have a Risk-Based Approach

The current ATP design does not consider risk to prioritize and select antimicrobial products for testing. The ATP has consistently focused on testing tuberculocides and hospital disinfectant products to ensure efficacy post registration. The ATP design considers all hospital-level disinfectants equal in their importance to controlling environmental transmission of infectious microorganisms. Further, the EPA intended to test all registered tuberculocides and hospital disinfectant products. However to date, according to the agency's website, all of the registered tuberculocides and hospital disinfectants have not been tested. According to the agency, with over 600 hospital disinfectants registered and a capacity for testing a limited number of products every year, it struggled to get through all products in the market.

Despite having limited testing capacity, the ATP is not designed to target products for testing based on risks to public health. For example, the ATP currently does not take into account product label claims or CDC prevalence data when determining which products to test. Furthermore, while the EPA currently focuses its ATP efficacy testing on tuberculocides and hospital disinfectant products, the microorganisms of greatest concern for healthcare-associated infections are not specifically tested in the ATP. For example, *Clostridium difficile* (*C. diff*) has become an increasing public health concern; however, testing the efficacy of label claims associated with *C. diff* is not part of the scope of the ATP. Healthcare-associated infection prevalence data could be an important consideration for EPA decisions on which products to target for testing.

Clostridium difficile: A Public Health Concern

Clostridium difficile (C. diff) is a bacterium that causes inflammation of the colon, known as colitis. *C.diff* became an increasing public health concern between 2007 and 2008. According to the CDC, *C.diff* is responsible for 337,000 infections and 14,000 deaths in the United States every year. In 2009, the agency issued interim guidelines to evaluate the effectiveness of any product applying for a *C.diff* claim. This guidance was updated in June 2014. According to the agency, of the over 600 registered hospital disinfectants, 48 products have label claims for efficacy against *C.diff.*



Medical illustration of *Clostridium difficile*. (CDC image)

Additionally, the agency could consider other risk factors—such as compliance history, sales and production data, and historical testing data—when determining which products should be tested in a given year. The agency is currently considering the future direction of the ATP and making an allowance for a

redesign of the program. ATP staff have acknowledged that having a targeted sampling approach should be part of their redesign. A risk-based prioritization for future testing would provide a roadmap for which disinfectants to target.

To further ensure that the agency targets the most critical products to be tested in the ATP, some factors to consider when developing a risk-based review process are outlined below.

Factors That Could be Considered by the EPA in Conducting a Risk-Based Sampling Approach

- Compliance history.
- Historical test data.
- Re-registration efficacy data.
- Sales data.
- Production data.
- Distributor products.
- Organisms that cause healthcare-associated infections.
- Public health priority areas.
- CDC prevalence data.
- Development of new testing methods.
- Elapsed time since last EPA review.
- Product label claims.
- Product use site.

Conclusion

The ATP is intended to help protect public health by ensuring that registered hospital disinfectants and tuberculocides in the marketplace continue to meet stringent efficacy standards. Although the program as currently designed and conducted does not assure that most hospital disinfectant products continue to be effective, at this point it is redundant and unnecessary to make adjustments, since the EPA is concurrently having the products re-registered. However, following re-registration, the EPA needs to implement a risk-based strategy for a post registration testing regime. The strategy needs to assure that antimicrobial products used in hospital settings remain effective while in the marketplace. The strategy also needs to deter and detect noncompliance, to ensure that hospital-level disinfectants continue to work as labelled to protect public health.

Recommendations

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

1. Suspend administering the current Antimicrobial Testing Program until completion of the one-time re-registration process.

2. Develop a risk-based antimicrobial testing strategy to assure the effectiveness of public health pesticides used in hospital settings once products are in the marketplace. At a minimum, the strategy should:

a. Include a framework for periodic testing to assure products continue to be effective after registration.
b. Define a program scope that is flexible and responsive to current and relevant public health risks.
c. Identify risk factors for selecting products to test.
d. Identify the method to be used for obtaining samples for testing.
e. Designate a date to commence risk-based post-registration testing.

Agency Response and OIG Evaluation

The agency agreed with our findings and recommendations, and provided corrective actions and estimated completion dates that meet the intent of the recommendations. Based on the agency's written response, the recommendations are resolved and open with corrective actions ongoing. No further response to this report is required. The agency's detailed response is in Appendix B. The agency also provided technical comments on the draft report, which we incorporated into our final report as appropriate.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Potential Monetary Benefits (in $000s)
1	10	Suspend administering the current Antimicrobial Testing Program until completion of the one-time re-registration process.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	11/30/17	
2	10	Develop a risk-based antimicrobial testing strategy to assure the effectiveness of public health pesticides used in hospital settings once products are in the marketplace. At a minimum, the strategy should: a. Include a framework for periodic testing to assure products continue to be effective after registration. b. Define a program scope that is flexible and responsive to current and relevant public health risks. c. Identify risk factors for selecting products to test. d. Identify the method to be used for obtaining samples for testing. e. Designate a date to commence risk-based post-registration testing.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	11/30/18	

[1] O = Recommendation is open with agreed-to corrective actions pending.
C = Recommendation is closed with all agreed-to actions completed.
U = Recommendation is unresolved with resolution efforts in progress.

Appendix A

Details on Scope, Methodology and Prior Reports

In support of the objective, we reviewed the FIFRA, relevant background information, guidance documents and efficacy testing standards. Specifically, we reviewed the Pesticide Registration Manual relating to antimicrobial registration. We reviewed the EPA Strategic Plan for fiscal years 2014–2018, and relevant budget information. We reviewed reports and data in support of the status of products tested and products needing to be tested. We analyzed the status of the ATP list of products tested on the EPA website. We gathered data on the most recent samples tested and actions taken based on the testing results. We obtained information and guidance documents on recent upgrades made to testing methods and the pesticide re-registration process.

We interviewed staff in the Office of Pesticide Programs' Antimicrobial Division involved in administering the ATP. We also met with an Office of Enforcement and Compliance Assurance staff member to obtain an understanding of their role and activities regarding the oversight of antimicrobials and the ATP.

The Office of Pesticide Programs requested our assistance in reviewing future design options for ATP, and requested guidance in developing the future direction of the ATP. In response to this request, the objective of fieldwork was to evaluate options for meeting the goals and intent of the ATP. To answer the objective of determining which option is the most beneficial for improving the EPA's ATP, we reviewed the existing testing program and evaluated the proposed options for costs, stakeholders and agency's considerations. We reviewed the options provided by the agency to see if:

- The option was consistent with the statement mission.
- The design option would address the risk that product formulations could change over time.

During our discussions with the EPA, Office of Pesticide Programs staff provided us with potential options in redesigning the ATP. We also gathered information from the Office of Pesticide Programs' Biological and Economic Analysis Division regarding its role, capacity and resource capabilities under the options being considered. We reviewed the options based on the information provided by the agency. Additionally, we met with external stakeholders, including manufacturers, an organization that represents end-users of hospital disinfectant products, and staff from the CDC.

Prior Reports

U.S. Government Accountability Office (GAO) Report No. RCED-90-139*, Disinfectants: EPA Lacks Assurance They Work*, issued August 30, 1990: GAO found that the EPA did not know whether disinfectants kill the germs claimed on product labels. GAO reported that market forces cannot be relied upon to control disinfectant efficacy problems because users cannot visually identify ineffective products. GAO also found that the EPA lacked an enforcement strategy to ensure that, once registered, disinfectants sold and distributed in the marketplace

worked as claimed on product labels. GAO noted that historical enforcement and other data estimated that 20 percent of disinfectants on the market did not work as claimed, posing health risks to users. The ATP program was initiated in response to this GAO report.

EPA OIG Report No. 09-P-0152*, Results of Hotline Complaint Review of EPA's Antimicrobial Testing Program*, issued May 27, 2009: In 2008, the OIG received a hotline allegation that the Antimicrobial Division was withholding information on product failures from its intended users. The report concluded that the hotline claim was unsubstantiated. The report did not contain any recommendations.

EPA OIG Report No. 11-P-0029*, EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products*, issued December 15, 2010: This report recommended that the EPA improve its ATP program by redesigning its process to verify antimicrobial effectiveness. The EPA issued a letter in February 2012 stating that all agreed-to actions had been completed.

EPA OIG Report No. 15-P-0064*, Quick Reaction Report: Complete and Clear Information on the Effectiveness of Ebola Disinfectants Will Better Inform the Public*, issued January 21, 2015: The OIG found that the EPA's web pages should have ongoing, clear information about the effectiveness of disinfectants for use against the Ebola virus. The report included recommendations to modify EPA web page information to indicate the status of the EPA's ATP testing on all products listed, and that product testing status was clearly reported. The agency agreed with the recommendations and completed corrective actions prior to issuance of the report.

Appendix B

Agency's Response

August 24, 2016

MEMORANDUM

SUBJECT: OCSPP's Comments on the OIG's Draft Report: "EPA Needs a Risk-Based Strategy to Assure Continued Effectiveness of Hospital-Level Disinfectants" Project No. OPE-FY16-0001

FROM: James J. Jones, 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) Draft Report entitled "EPA Needs a Risk-Based Strategy to Assure Continued Effectiveness of Hospital-Level Disinfectants." The Office of Chemical Safety and Pollution Prevention (OCSPP) appreciates the OIG's evaluation of EPA's Antimicrobial Testing Program (ATP) to determine whether the program ensures the efficacy of EPA-registered hospital sterilants,[1] disinfectants and tuberculocides; and to evaluate options for improving the program.

The OCSPP welcomes the Draft Report recommendations for redesigning the ATP with a risk-based testing strategy. We agree that the recommendations will improve the program's effectiveness and that the combination of the on-going antimicrobial re-registration process and the revised Use Dilution Method will increase the quality of the efficacy data supporting hospital disinfectant product registrations. In a separate document, OCSPP is also providing the OIG with Technical Comments on the Draft Report. We plan to implement the recommendations, as detailed in the following:

I. OCSPP's Response to the Recommendations

Recommendation 1: Suspend administering the current ATP until completion of the re-registration process.

- **OCSPP Response**: The OCSPP agrees with the OIG's recommendation to suspend the current ATP program until completion of the re-registration process. We agree with the OIG report noting the redundancy of the ATP program with the antimicrobial re-

[1] Sterilant testing was completed in 1993. In 1996, regulatory authority for certain liquid chemical sterilant products was transferred to the Food and Drug Administration.

registration process. Through the submittal of a combination of new studies and citation of higher quality studies, the re-registration program will increase the level of confidence in the efficacy data supporting all hospital disinfectant product registrations. Furthermore, the re-registration regulatory process enables the EPA to upgrade the information supporting many products over a short period of time in contrast to the current ATP. The Office of Pesticide Programs (OPP) will develop a plan to coordinate and implement the discontinuation of the present-day ATP.

Timeframe: OCSPP will close the ATP program by November 2017.

OIG Recommendation 2: Develop a risk-based strategy to assure the effectiveness of public health pesticides used in hospital settings once products are in the marketplace. At a minimum, the strategy should:

a. Include a framework for periodic testing to assure products continue to be effective after registration.
b. Define a program scope that is flexible and responsive to current and relevant public health risks.
c. Identify risk factors for selecting products to test.
d. Identify the method to be used for obtaining samples for testing.
e. Designate a date to commence risk-based post-registration testing.

OCSPP Response: The OCSPP agrees with the OIG's recommendation that a risk-based strategy is needed to assure the effectiveness of public health pesticides used in hospital settings once products are in the marketplace. In developing a risk-based strategy, the program will consider all five recommendations listed in the OIG report. OCSPP will consider developing the strategy using a two-year phased approach – defining the criteria for completing recommendations stated in (a) and (b) in the first year, and defining the criteria for completing recommendations stated (c), (d) and (e), in the second year.

Timeframe: By November 2018, OCSPP will develop a risk-based strategy to assure the effectiveness of public health pesticides used in hospital settings once products are in the marketplace.

II. Conclusion and Contact Information:

Overall, OCSPP is pleased with the thoughtful nature of the OIG's Draft Report in providing direction regarding the future of the ATP, and looks forward to the implementation of the recommendations.

If you have any technical questions regarding these responses, please contact Jennifer McLain, OPP, mclain.jennifer@epa.gov. If you have other questions, please contact Janet Weiner, OCSPP's Audit Liaison, at weiner.janet@epa.gov.

Appendix C

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