



U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL



Chemical Safety

Quick Reaction Report: Complete and Clear Information on the Effectiveness of Ebola Disinfectants Will Better Inform the Public

Report No. 15-P-0064

January 21, 2015



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Report Contributors:

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Abbreviations

ATP	Antimicrobial Testing Program
CDC	Centers for Disease Control and Prevention
EPA	U.S. Environmental Protection Agency
OIG	Office of Inspector General

Cover photo: A training participant with a jug of chlorinated disinfectant prepares to demonstrate how to properly carry out a disinfection procedure.
(Centers for Disease Control and Prevention photo)

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At a Glance

Why We Did This Review

This is a quick reaction report that addresses the completeness and consistency of information provided on the U.S. Environmental Protection Agency's (EPA) website regarding disinfectants for use against the Ebola virus. The EPA's Web page <http://www.epa.gov/oppad001/lis-t-l-ebola-virus.html>, titled *Disinfectants for Use Against the Ebola Virus*, contains a list of registered disinfectants that meet the Centers for Disease Control and Prevention (CDC) criteria for hospital disinfectants. This list is also known as List L.

Disinfectants like those on List L are regulated and registered by the EPA. During the registration process, the EPA reviews data submitted by manufacturers to verify that products with a public health claim are effective. The EPA also has its own testing program—the Antimicrobial Testing Program (ATP)—which tests the effectiveness of products after they are registered.

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

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

Send all inquiries to our public affairs office at (202) 566-2391 or visit www.epa.gov/oig.

The full report is at: www.epa.gov/oig/reports/2015/20150121-15-P-0064.pdf

Quick Reaction Report: Complete and Clear Information on the Effectiveness of Ebola Disinfectants Will Better Inform the Public

What We Found

As of December 2014, the EPA's List L Web page included 192 disinfectants that meet CDC criteria for use against the Ebola virus. The EPA's List L Web page contains the name of the disinfectant product (e.g., Clorox®), and whether the product can be used in hospital and health care settings, offices, schools and residential settings. Of the 192 products listed, 29 recently registered products (registered since 2010) have not been tested for effectiveness by the ATP. This status is not disclosed on the List L Web page.

The EPA's Web pages should have ongoing, clear information about the effectiveness of disinfectants for use against the Ebola virus.

In addition, we identified eight products on List L that are not listed on the ATP Web page <http://www.epa.gov/oppad001/antimicrobial-testing-program.html>. According to the EPA, three of the eight products were recently registered and had not been posted to the ATP Web page. The other five products had been tested by the ATP; however, their testing status was missing from the ATP page.

A 2010 report by the EPA Office of Inspector General found that many antimicrobial products, such as disinfectants, scheduled to be tested by the EPA's ATP were not tested. Of those that were tested for effectiveness, the failure rate was high. The EPA has now tested more products. According to the EPA, the lack of ATP testing on recently registered products does not pose any risk to the public due to enhanced manufacturer testing requirements for recently registered products. However, the testing results designed to demonstrate whether products work as claimed by manufacturers are not being communicated clearly.

Recommendations and Agency Corrective Actions

We recommended that the Assistant Administrator for Chemical Safety and Pollution Prevention modify the List L Web page information to indicate the status of the EPA's ATP testing on all products listed. We also recommended that the EPA ensure that all List L products are included on the ATP list, and product testing status is clearly reported.

The agency agreed with our recommendations and has completed actions to address them. Both recommendations are closed.



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

THE INSPECTOR GENERAL

January 21, 2015

MEMORANDUM

SUBJECT: Quick Reaction Report: Complete and Clear Information on the Effectiveness of Ebola Disinfectants Will Better Inform the Public
Report No. 15-P-0064

FROM: Arthur A. Elkins Jr.

A handwritten signature in black ink, appearing to read "Arthur A. Elkins Jr.", is written over the printed name.

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

This is a quick reaction report prepared by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). The report addresses information the EPA provides to the public regarding disinfectants for use against the Ebola virus. 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 office responsible for the issues evaluated in this report is the Office of Pesticide Programs within the EPA's Office of Chemical Safety and Pollution Prevention.

You are not required to provide a written response to this report because you have completed agreed-to corrective actions for the report recommendations. Both recommendations have been closed. 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.

We will post this report to our website at <http://www.epa.gov/oig>.

Purpose, Scope and Methodology

This is a quick reaction report that addresses improvements needed in information provided by the U.S. Environmental Protection Agency (EPA) on its website regarding disinfectants that are for use against the Ebola virus. We reviewed the completeness and consistency of EPA's public information on disinfectants for use against the Ebola virus and efficacy testing results on those disinfectants.

We conducted this review from November 2014 to January 2015 in accordance with generally accepted government auditing standards, with the following exceptions:

- We abbreviated our normal project planning and reporting steps, as well as outreach to the EPA, to expedite our work due to the ongoing Ebola outbreak in Africa and the corresponding interest in treatment information in the United States.
- We did not evaluate findings or conclusions in connection with internal controls as they relate to the EPA's Ebola disinfectants Web pages.

The departure from generally accepted government auditing standards has no impact on the conclusions drawn on the information provided in this report.

Background

Antimicrobials are designed to destroy or suppress harmful bacteria, viruses, and other microorganisms on inanimate objects and surfaces in hospitals and other settings. Antimicrobials are regulated and registered under the Federal Insecticide, Fungicide, and Rodenticide Act by the EPA's Office of Pesticide Programs. During the registration process, the EPA reviews test data submitted by manufacturers to verify that products with a public health claim are effective. The agency's Antimicrobial Testing Program (ATP) is a post-registration efficacy testing program. The ATP determines whether products in the marketplace are effective and continue to perform in a manner consistent with the product's initial registration.

According to the Centers for Disease Control and Prevention (CDC) Web pages, there are currently no products claiming on their label to kill the Ebola virus. However, the CDC's website states:

... [V]iruses such as Ebola are susceptible to a broad range of hospital disinfectants used to disinfect hard, non-porous surfaces. As a precaution, selection of a disinfectant product with a higher potency than what is normally required for a virus (such as Ebola) is being recommended.

The CDC issued guidance documents¹ about the cleaning and decontamination of Ebola. For example, the CDC's *Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus*² states:

¹ <http://www.cdc.gov/vhf/ebola/prevention/cleaning-and-decontamination.html>

² <http://www.cdc.gov/vhf/ebola/hcp/environmental-infection-control-in-hospitals.html>

Use a U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant with a label claim for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus) to disinfect environmental surfaces in rooms of patients with suspected or confirmed Ebola virus infection.

The CDC also provides a link to the EPA Web page³ titled *Disinfectants for Use Against the Ebola Virus*, which contains a listing of registered disinfectants that meet CDC criteria. The list is also known as List L, and was created by the EPA to provide easily accessible information on currently marketed products that can be used against the Ebola virus and on their appropriately labeled use sites. List L is also referenced in the various CDC guidance documents regarding cleaning and decontamination of Ebola.

Prior OIG Report

EPA Office of Inspector General (OIG) Report No. 11-P-0029, *EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products*,⁴ was 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.

Recent Agency Actions Prompted by OIG Work

On November 21, 2014, the OIG contacted the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention to provide information on a time-sensitive issue concerning List L. The OIG noted that List L contained two products where “Agency Taking Action”⁵ was mentioned; therefore, those two products were not confirmed as effective. Although one product had been removed from List L shortly after the OIG’s November 2014 notification, the other product remained on List L.

Because of the significance of List L and broad public attention and concern about Ebola, the OIG suggested that the EPA remove the remaining product from List L because “an ATP designation of ‘Agency Taking Action’ is not wholly consistent with listing a product on List L, and could be misleading to those who rely on EPA’s List L designations.” The EPA responded promptly, stating that the remaining product status had recently changed to “Agency Confirmed Efficacy.” By November 24, 2014, the EPA updated the List L Web page to reflect the product’s status change.

Information on Testing of Ebola Disinfectants Will Better Inform Public

As of December 2014, the EPA’s List L Web page included 192 disinfectants that meet CDC criteria for use against the Ebola virus. The List L Web page contains the name of the

³ <http://www.epa.gov/oppad001/list-l-ebola-virus.html>

⁴ <http://www.epa.gov/oig/reports/2011/20101215-11-P-0029.pdf>

⁵ According to the ATP Web page <http://www.epa.gov/oppad001/antimicrobial-testing-program.html>, “Agency Taking Action” means “products under EPA deliberation, including undergoing testing or review, or taking regulatory or enforcement action.”

disinfectant product (e.g., Clorox®), and whether the product can be used in hospital and health care settings, offices, schools and residential settings. Of the 192 products listed, 29 recently registered products (registered since 2010) have not been tested for effectiveness by the EPA's ATP. This status is not disclosed on the List L Web page.

In addition, we identified eight products on List L that are not listed on the ATP Web page. According to the EPA, three of the eight products were recently registered products and had not been posted to the ATP Web page. The other five products had been tested by the ATP; however, their testing status was missing from the ATP Web page.

The EPA OIG's 2010 report, *EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products*, found that many antimicrobial products, such as disinfectants, scheduled to be tested by the EPA's ATP were not tested. Of those products that were tested for effectiveness, the failure rate was high. The EPA has now tested more products. According to the EPA, the lack of ATP testing on recently registered products does not pose any risk to the public due to enhanced manufacturer testing requirements for recently registered products. However, the testing results designed to demonstrate whether products work as claimed by manufacturers are not being communicated clearly.

Recommendations

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

1. Modify the EPA's List L Web page information to indicate the status of the EPA's ATP testing on all products listed.
2. Ensure that all List L products are included on the ATP list, and product testing status is clearly reported.

Agency Comments

EPA officials agreed with our recommendations and completed actions in response to both recommendations. The actions taken met the intent of the recommendations. Specifically, the EPA's List L Web page now contains a link to the ATP Web page. The agency also updated the ATP Web page to include missing List L products and their testing status. Both recommendations have been closed.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in \$000s)	
Rec. No.	Page No.	Subject	Status ¹	Action Official	Completion Date	Claimed Amount	Agreed-To Amount
1	3	Modify the EPA's List L Web page information to indicate the status of the EPA's ATP testing on all products listed.	C	Assistant Administrator for Chemical Safety and Pollution Prevention	12/8/14		
2	3	Ensure that all List L products are included on the ATP list, and product testing status is clearly reported.	C	Assistant Administrator for Chemical Safety and Pollution Prevention	1/7/15		

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.

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