U.S. Environmental Protection Agency
Office of Inspector General

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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.