U.S. Environmental Protection Agency
Office of Inspector General

11-P-0029
December 15, 2010

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.