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Results of EPA OIG's Review of EPA's Antimicrobial Testing Program

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On September 19, 2016, the U.S. Environmental Protection Agency's (EPA) Office of Inspector General (OIG) issued a report, *EPA Needs a Risk-Based Strategy to Assure Continued Effectiveness of Hospital-Level Disinfectants*, the result of OIG's review of 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." OIG found that the ATP "does not assure that hospital-level disinfectant products continue to be effective after they are registered," specifically that:

- 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.

- EPA relies on manufacturers to voluntarily submit product samples for testing. In the last three 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.

Importantly, however, OIG concludes: "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."

OIG makes two major recommendations:

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

2. EPA should 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, OIG states, the strategy should:

- Include a framework for periodic testing to assure products continue to be effective after registration.

- Define a program scope that is flexible and responsive to current and relevant public health risks.

- Identify risk factors for selecting products to test.

- Identify the method to be used for obtaining samples for testing.

- Designate a date to commence risk-based post-registration testing.

In its response, EPA agreed with OIG's recommendations, and stated it will develop a plan to coordinate and implement the discontinuation of the present-day program, with the closure of the ATP program to take place by **November 2017**. EPA also stated that by **December 2018** it plans to develop a risk-based strategy to assure the effectiveness of public health pesticides used in hospital settings once products are in the marketplace.

Registrants of the affected products should monitor closely the development of EPA's plans both to discontinue the program and to establish this new risk-based strategy for assuring product efficacy.

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