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Antimicrobial Product Evaluation Program (APEP) for Products with Public Health Claims in the Marketplace

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On June 21, 2018, during the U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) webinar, EPA discussed the new draft risk-based strategy for ensuring the performance of public health antimicrobial products and announced the intended replacement of the former Antimicrobial Testing Program (ATP) with the new Antimicrobial Product Evaluation Program (APEP). Comments on the draft risk-based strategy may be submitted to EPA until **July 16, 2018**.

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Public health antimicrobial products are those products that bear a claim to control microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user, including microorganisms infectious to people in any area of the inanimate environment. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires product performance (*i.e.*, efficacy) data to support registration of antimicrobial products bearing a public health claim.

EPA began the webinar with an overview of the Office of Inspector General (OIG) Report entitled "EPA Needs a Risk-Based Strategy to Assure Continued Effectiveness of Hospital-Level Disinfectants." Report #16-P-0316 (Sept. 19, 2016). OIG conducted a review of EPA's 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." *See* Bergeson & Campbell, P.C.'s article dated September 21, 2016, "Results of EPA OIG's Review of EPA's Antimicrobial Testing Program" for a full summary of the OIG report. In the 2016 report, OIG recommends OPP suspend administering the current ATP and develop a risk-based strategy to assure the effectiveness of public health pesticides used in hospital settings once products are in the marketplace. EPA agreed with OIG's recommendations.

EPA provided that "[t]he intent of the [APEP] is to ensure continued effectiveness of antimicrobial products with public health claims (hospital disinfectants, tuberculocides, and other health care claims) in the marketplace. The maintenance and development of technically-sound test methods, quality improvement tools (*e.g.*, peer review of new protocols), and outreach and stewardship activities will further support the program."

The risk-based testing strategy will ensure the effectiveness of public health pesticides used in hospital settings by:

- Establishing a framework for periodic testing after registration;
- Defining a program that is responsive to current public health risks;
- Identifying risk factors for selecting products to test;
- Establishing a process to be used for obtaining samples for testing; and

- Setting a date to begin risk-based post-registration testing.

Risk-based factors under consideration by EPA include:

- Use of healthcare-associated infection data reports;
- Claims against microorganisms of greatest concern to healthcare-associated infections (*e.g., Clostridium difficile, MRSA,VRE*);
- Emerging pathogens and homeland security considerations;
- Trends in previous ATP compliance history (*e.g.*, claims against *Mycobacterium bovis BCG*);
- Atypical label claims (*e.g.*, very short contact times, use sites and surfaces, new product delivery and application procedures);
- Claims not evaluated under the previous ATP;
- New and unusual active ingredients;
- Formulation chemistry-related issues (*e.g.*, shelf-life/stability once prepared, lack of expiration dates);
- Use of new or procedurally-revised test methods;
- Tips and complaints;
- Issues identified during reregistration (*e.g.*, frequency of repeat testing, acceptance criteria not met); and
- Link to other federal initiatives.

OIG recommends a functional program begin after registration review is completed in **2022**. According to OIG, the development of a solid, acceptable testing strategy is key -- the strategy must be finalized and communicated to regulated and public health communities. OIG specified other EPA outreach activities for the testing program that must be considered, *e.g.*, setting and clearly communicating goals and establishing the baseline reporting mechanisms.

EPA expects to release this final strategy in **November 2018** and seeks public input prior to implementation. Please submit your comments on this topic by **July 16, 2018**, to the Office of Pesticide Programs Docket, EPA-HQ-OPP-2018-0265 at https://www.regulations.gov.

For additional information, please visit https://www.epa.gov/pesticide-registration/antimicrobial-testing-program or https://www.epa.gov/pesticide-registration/webinar-risk-based-strategy-ensure-continued-effectiveness-hospital.

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