



Antimicrobial Efficacy Test Methods

2009 Edition

In the United States, registrants of antimicrobial products that claim to be effective against organisms of “public health” significance (human pathogens and some animal pathogens of significant economic significance), must submit data to EPA demonstrating efficacy to support their registrations. EPA verifies efficacy by collecting samples and testing them at EPA or state laboratories. Failure in these tests can mean fines and a requirement to delete public health claims from the label. The test method required for registration of hard surface disinfectants, and used in enforcement is known as the Use-Dilution Test (UDT). Notwithstanding its long term use, it has been criticized for decades by industry, academia, and in the published literature as a highly variable test method that yields unreliable and inaccurate results regarding the efficacy of antimicrobial products. The variability problems with the UDT can cause erroneous efficacy failures, resulting in registration issues and, in some situations, EPA enforcement actions that can result in removal of disinfectant products from the market.

The problem with the UDT has been the focus of significant attention among registrants of products making public health claims. Our firm has provided legal and technical support to a working group of disinfectant registrants in an effort to persuade EPA to alter the test method or its approach to enforcement. Among these activities are:

- Developing a comprehensive and rigorous study to identify the most significant sources of variability in the test method and modifications to improve its reliability;
- Identifying microbiology experts to peer-review the study and its conclusions, and to advocate the group’s recommendations for improving the test method before EPA;
- Reviewing the published literature to document the numerous studies showing substantial variability problems with the UDT and what has been done to try to improve the method; and
- Advocacy at EPA focused on the variability of the method and ways of reducing it.

This effort is ongoing and has resulted in a commitment by EPA to conduct a multi-laboratory collaborative study in 2009 designed to compare and evaluate a modified version of the UDT which should significantly improve the reliability and accuracy of the UDT. Steptoe is coordinating this study with the working group and EPA. The modified UDT will serve as an interim remedy until EPA is able to implement a new, more robust, reliable and reproducible test method to replace the UDT. This new method is under review by the OECD Task Force on Biocides with the view toward coordinated acceptance among all OECD member states. The new, quantitative, method should address many of the issues EPA and the regulated community in the United States face with the old UDT. However, the validation and acceptance process will take several years, and implementation will be a challenge to the whole industry.

To discuss the issues facing your business, please contact:

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