On September 29, 2017, the U.S. Environmental Protection Agency (EPA) announced the availability of two final test method Standard Operating Procedures (SOP) for evaluating the efficacy of antimicrobials against spores of *Clostridium difficile* (*C. diff*).

- **EPA Microbiology Laboratory Branch (MLB) SOP MB-28: Procedure for the Production and Storage of Spores of *Clostridium difficile* for Use in the Efficacy Evaluation of Antimicrobial Agents;** and
- **EPA MLB SOP MB-31: Procedure for the OECD Quantitative Method for Testing Antimicrobial Products against Spores of *Clostridium difficile* (ATCC 43598) on Inanimate, Hard, Non-porous Surfaces.**

EPA also released regulatory guidance for test criteria and pesticide claims for these products, specifically “**Methods and Guidance for Testing the Efficacy of Antimicrobial Products Against Spores of *Clostridium difficile* on Hard Non-Porous Surfaces.**” These test methods and guidance provide a framework for registrants who seek to make a claim for antimicrobial pesticide products to control these spores on hard, non-porous surfaces.

*C. diff* is an anaerobic, spore-forming bacterium and a frequent cause of hospital-acquired infections. The spores survive on hard surfaces such as glass, metals, and plastics that are commonly found in health-care settings. Antimicrobial pesticides are used to reduce the number of spores on environmental surfaces. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the registrant of an antimicrobial product with a public health claim is required to submit efficacy data to EPA in support of the product’s registration.

EPA MLB SOP MB-28 describes the test methodology for producing and storing standardized spore suspensions of *C. diff* based on ASTM E2839, Standard Test Method for Production of *C. difficile* Spores for Use in Efficacy Evaluation of Antimicrobial Agents (ASTM International). A spore suspension should be developed and qualified according to EPA MLB SOP MB-28 before an efficacy evaluation can be performed using method EPA MLB SOP MB-31. EPA MLB SOP MB-31 describes a quantitative method intended for evaluating the sporicidal efficacy of liquid disinfectants against spores of *C. diff* on inanimate, hard, non-porous surfaces.

EPA solicited comments on the clarity of the test method SOPs and the regulatory guidance in December 2016. EPA received comments from twelve entities and revised the drafts to incorporate suggested changes. EPA posted its response to those comments in Docket No. EPA-HQ-OPP-2016-0753-0026. EPA also is working with ASTM International, a standard-setting organization, on adoption of these test methods as official ASTM standards.

EPA’s response to comments and other documents associated with this action are available in **Docket No. EPA-HQ-OPP-2016-0753**.
HQ-OPP-2016-0753 at www.regulations.gov. The methods and guidance also are found on EPA’s Antimicrobial Testing Methods & Procedures Developed by EPA’s Microbiology Laboratory webpage, at the Methods tab as Method IDs MB-28 and MB-31, and at the Guidance tab as Sporicidal Claims Against *Clostridium difficile*.

**Commentary**

*C. diff* infections, spread by transmission of bacterial spores, are a wide-spread problem in healthcare settings in particular and have proven difficult to prevent. *C. diff* is one of the most common causes of healthcare-acquired infection. More EPA FIFRA registered sporicidal disinfectants are needed to support prevention efforts targeting the development of *C. diff* clusters and outbreaks. EPA’s new guidance and test methods will clarify the registration process for such products, and thereby aid healthcare facilities in their identification of products proven to significantly reduce *C. diff* spores and help with prevention efforts.

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