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# Regulatory Framework for Disinfectants and Sterilants

DISINFECTION AND STERILIZATION GUIDELINE  
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Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

## AT A GLANCE

Regulatory framework for disinfectants and sterilants from the Guideline for Disinfection and Sterilization in Healthcare Facilities (2008).

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## Overview

Before using the guidance provided in this document, healthcare workers should be aware of the federal laws and regulations that govern the sale, distribution, and use of disinfectants and sterilants. In particular, health-care workers need to know what requirements pertain to them when they apply these products. Finally, they should understand the relative roles of EPA, FDA, and CDC so the context for the guidance provided in this document is clear.



## EPA and FDA

In the United States, chemical germicides formulated as sanitizers, disinfectants, or sterilants are regulated in interstate commerce by the Antimicrobials Division, Office of Pesticides Program, EPA, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947, as amended <sup>792</sup>. Under FIFRA, any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest (including microorganisms but excluding those in or on living humans or animals) must be registered before sale or distribution. To obtain a registration, a manufacturer must submit specific data about the safety and effectiveness of each product. For example, EPA requires manufacturers of sanitizers, disinfectants, or chemical sterilants to test formulations by using accepted methods for microbiocidal activity, stability, and toxicity to animals and humans. The manufacturers submit these data to EPA along with proposed labeling. If EPA concludes the product can be used without causing "unreasonable adverse effects," then the product and its labeling are registered, and the manufacturer can sell and distribute the product in the United States.

FIFRA also requires users of products to follow explicitly the labeling directions on each product. The following standard statement appears on all labels under the "Directions for Use" heading: "It is a violation of federal law to use this product in a manner inconsistent with its labeling." This statement means a health-care worker must follow the safety precautions and use directions on the labeling of each registered product. Failure to follow the specified use-dilution, contact time, method of application, or any other condition of use is considered a misuse of the product and potentially subject to enforcement action under FIFRA.

In general, EPA regulates disinfectants and sterilants used on environmental surfaces, and not those used on critical or semicritical medical devices; the latter are regulated by FDA. In June 1993, FDA and EPA issued a "Memorandum of Understanding" that divided responsibility for review and surveillance of chemical germicides between the two agencies. Under the agreement, FDA regulates liquid chemical sterilants used on critical and semicritical devices, and EPA regulates disinfectants used on noncritical surfaces and gaseous sterilants <sup>793</sup>. In 1996, Congress passed the Food Quality Protection Act (FQPA). This act amended FIFRA in regard to several types of products regulated by both EPA and FDA. One provision of FQPA removed regulation of liquid chemical sterilants used on critical and semicritical medical devices from EPA's jurisdiction, and it now rests solely with FDA <sup>792, 794</sup>. EPA continues to register nonmedical chemical sterilants. FDA and EPA have considered the impact of FQPA, and in January 2000, FDA published its final guidance document on product submissions and labeling. Antiseptics are considered

antimicrobial drugs used on living tissue and thus are regulated by FDA under the Food, Drug and Cosmetic Act. EPA regulates disinfectants, sterilants and high-level disinfectants intended to process critical and semicritical devices. FDA has published test methods that manufacturers should submit to FDA for 510[k] clearance for such agents.



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## CDC

At CDC, the mission of the Coordinating Center for Infectious Diseases is to guide the public on how to prevent and respond to infectious diseases in both health-care settings and at home. With respect to disinfectants and sterilants, part of CDC's role is to inform the public (in this case healthcare personnel) of current scientific evidence pertaining to these products, to comment about their safety and efficacy, and to recommend which chemicals might be most appropriate or effective for specific microorganisms and settings.


## Test Methods

The methods EPA has used for registration are standardized by the AOAC International; however, a survey of scientific literature reveals a number of problems with these tests that were reported during 1987–1990<sup>58, 76, 80, 428, 736, 737, 795-800</sup> that cause them to be neither accurate nor reproducible<sup>416, 737</sup>. As part of their regulatory authority, EPA and FDA support development and validation of methods for assessing disinfection claims<sup>801-803</sup>. For example, EPA has supported the work of Dr. Syed Sattar and coworkers who have developed a two-tier quantitative carrier test to assess sporicidal, mycobactericidal, bactericidal, fungicidal, virucidal, and protozoacidal activity of chemical germicides<sup>701, 803</sup>. EPA is accepting label claims against hepatitis B virus (HBV) using a surrogate organism, the duck HBV, to quantify disinfectant activity<sup>124, 804</sup>. EPA also is accepting labeling claims against hepatitis C virus using the bovine viral diarrhea virus as a surrogate.

For nearly 30 years, EPA also performed intramural preregistration and postregistration efficacy testing of some chemical disinfectants in its own laboratories. In 1982, this was stopped, reportedly for budgetary reasons. At that time, manufacturers did not need to have microbiologic activity claims verified by EPA or an independent testing laboratory when registering a disinfectant or chemical sterilant<sup>805</sup>. This occurred when the frequency of contaminated germicides and infections secondary to their use had increased<sup>404</sup>. Investigations demonstrating that interlaboratory reproducibility of test results was poor and manufacturers' label claims were not verifiable<sup>416, 737</sup> and symposia sponsored by the American Society for Microbiology<sup>800</sup> heightened awareness of these problems and reconfirmed the need to improve the AOAC methods and reinstate a microbiologic activity verification program. A General Accounting Office report entitled *Disinfectants: EPA Lacks Assurance They Work*<sup>806</sup> seemed to provide the necessary impetus for EPA to initiate corrective measures, including cooperative agreements to improve the AOAC methods and independent verification testing for all products labeled as sporicidal and disinfectants labeled as tuberculocidal. For example, of 26 sterilant products tested by EPA, 15 were canceled because of product failure. A list of products registered with EPA and labeled for use as sterilants or tuberculocides or against HIV and/or HBV is available through EPA's website at [This link is no longer active: <http://www.epa.gov/oppad001/chemregindex.htm>External ]. The current version of this document may differ from original version: [Selected EPA-registered Disinfectants](#)External ]. Organizations (e.g., Organization for Economic Cooperation and Development) are working to standardize requirements for germicide testing and registration.

## Neutralization of Germicides

One of the difficulties associated with evaluating the bactericidal activity of disinfectants is prevention of bacteriostasis from disinfectant residues carried over into the subculture media. Likewise, small amounts of disinfectants on environmental surfaces can make an accurate bacterial count difficult to get when sampling of the health-care environment as part of an epidemiologic or research investigation. One way these problems may be overcome is by employing neutralizers that inactivate residual disinfectants<sup>807-809</sup>. Two commonly used neutralizing media for chemical disinfectants are Letheen Media and D/E Neutralizing Media. The former contains lecithin to neutralize quaternaries and polysorbate 80 (Tween 80) to neutralize phenolics, hexachlorophene, formalin, and, with lecithin, ethanol. The D/E Neutralizing media will neutralize a broad spectrum of antiseptic and disinfectant chemicals, including quaternary ammonium compounds, phenols, iodine and chlorine compounds, mercurials, formaldehyde, and glutaraldehyde<sup>810</sup>. A review of neutralizers used in germicide testing has been published<sup>808</sup>.

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[National Center for Emerging and Zoonotic Infectious Diseases \(NCEZID\)](#)

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