Exploration of the Disinfection Hierarchy

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The Agency is considering the approach for regulatory purposes:

- Provide more expeditious guidance to health care officials and the public on the most effective type of registered antimicrobial products on the market to use against an emerging pathogen
- Increase the efficiency of and lower resources associated with registering antimicrobial pesticides while maintaining a high level of public health protection
THE PURPOSE OF THE WORKSHOP

- Provide a forum for scientific experts and stakeholders to discuss:
  - the current science on which the disinfection hierarchy concepts are based
  - scientific issues that may present challenges for its use registering antimicrobial pesticide products and
  - ideas on how to address these issues
DISINFECTION HIERARCHY CONCEPT

Though microbial death rate is usually constant for a particular agent acting against a single microbe, death rates do vary—sometimes dramatically—among microorganisms and viruses. Generally these microbes fall along a continuum from most susceptible to most resistant to antimicrobial agents.
DISINFECTION HIERARCHY CONCEPT

- Describes a general order of susceptibility of various classes of microorganisms to antimicrobial chemicals.
- Different classes of microorganisms exhibit different degrees of susceptibility due to biochemical and biophysical characteristics of the organism.

![Microbiological Hierarchy](image)

* Figure 1. Microbiological disinfection hierarchy. Examples of microorganisms in each category are provided.*
DISINFECTION HIERARCHY APPLICATIONS

Applied vertically down all microorganism classes from least to most susceptible to disinfection

Most Resistant
- Bacterial endospores
- Mycobacteria
- Cysts of protozoa
- Active stage protozoa
- Gram negative bacteria
- Fungi
- Non-enveloped
- Gram-positive bacteria
- Enveloped viruses

Most Susceptible
DISINFECTION HIERARCHY APPLICATIONS

- Representative microorganism[s] (hardest to kill within the class) are used to evaluate the efficacy of an antimicrobial product against each microorganism class.
- If an antimicrobial pesticide displays acceptable efficacy against the defined representative microorganisms(s) for a class, one may conclude that it is also effective against other microbes in the class that are deemed more susceptible.
The Agency is currently updating the existing emerging viral pathogens guidance to streamline the process for making certain disinfectant claims against these pathogens.

Emerging pathogens are usually not present on many disinfectant product labels and/or commercially available for testing.
Based upon the Spaulding Classification model, EPA will use a descending order of resistance system among viral organisms to determine the efficacy of an EPA registered disinfectant product once the emerging virus taxonomy has been identified. EPA will use broad viral groups to determine a product’s predicted efficacy against the emerging pathogens.

Most Resistance
- Small, Non-Envelope Viruses
- Large, Non-Envelope Viruses
- Envelope Viruses

Least Resistance
This process benefits the Agency by increasing the availability of disinfectant products for use during a public health threat.

Viral pathogens must be implicated in a public health outbreak by CDC to be used in this process.

Guidance allows registrants to make off-label claims [e.g., technical literature, website posting, consumer info sources] against emerging viral pathogens if product has data for harder to kill viruses.

Off-label claim language against the emerging pathogen is limited by the guidance.