

Current Regulatory Use of Disinfection Hierarchy Concept

- ▶ Agency considering expanding its application of the hierarchy approach
 - ▶ Increase the efficiency of and lower resource use associated with registering antimicrobial pesticides while maintaining a high level of public health protection
 - ▶ 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

Overview of efficacy data requirements

- ▶ Registrants must submit product-specific efficacy data to support the public health claim categories (sterilant, disinfectant, sanitizer) they would like to have on their product label
- ▶ We require data on specific representative organisms for each antimicrobial claim category

Overview of efficacy data requirements

- ▶ Disinfectants for Use on Hard Surfaces, Guideline 810.2200 – efficacy testing against designated representative organisms (e.g., *S. aureus*, *P. aeruginosa* and/or *S. enterica*):
 - ▶ Disinfectant claim category (hospital disinfectant, broad-spectrum, limited-spectrum)
 - ▶ Additional bacteria with reduced testing requirements (fewer test batches and carriers)

Overview of efficacy data requirements

- ▶ Sanitizers for Use on Hard Surfaces, Guideline 810.2300 – efficacy testing against designated representative organisms allows:
 - ▶ Non-food contact surface sanitizer or food contact surface sanitizer claims
 - ▶ Additional bacteria with reduced testing requirements (fewer test batches)

Overview of efficacy data requirements

- ▶ Once requirements for general claim category have been met registrants may also submit efficacy data for additional organisms, including additional bacteria, fungi, or viruses
- ▶ Additional organism data is organism-specific
- ▶ Additional bacteria have a reduced testing requirement compared to the representative organism testing

Use of Disinfection Hierarchy Approach

- ▶ Agency uses representative organisms in the existing regulatory scheme
 - ▶ To support general antimicrobial label claims (e.g., Disinfectant, Sanitizer) and allow reduced testing for additional organisms
 - ▶ For the emerging viral pathogens assessment process
 - ▶ For bridging (citing) efficacy data performed with a bulk liquid to support towelette product

Use of Disinfection Hierarchy Approach with Emerging Pathogens

- ▶ Use with the emerging viral pathogens guidance document
 - ▶ Guidance allows registrants to make off-label claims against emerging viral pathogens if product has data for harder to kill viruses
 - ▶ Guidance uses three viral categories -
 - ▶ small, non-enveloped viruses
 - ▶ large non-enveloped viruses
 - ▶ enveloped viruses

Use of Disinfection Hierarchy Approach with Emerging Pathogens

- ▶ Use with the emerging viral pathogens guidance document
 - ▶ Process allows efficacy data on a more resistant viral category to support limited product efficacy claims against an emerging or re-emerging viral pathogen (e.g., efficacy data on large, non-enveloped virus may support claims against enveloped emerging pathogen)

Disinfection Hierarchy Approach with Towelette Data Requirements

- ▶ Use with bridging (citing) efficacy data performed with a bulk (source) liquid to support towelette product
 - ▶ Full testing of representative bacterial organisms using towelette allows claims against all vegetative bacteria on the bulk liquid label (except *M. bovis*)
 - ▶ Full testing of base fungal organism (*T. mentagrophytes*) allows claims against all fungal organisms on the bulk liquid label
 - ▶ Full testing of the hardest-to-kill virus (using small, non-enveloped/ large, non-enveloped/ enveloped virus scheme) allows claims against all viruses on the bulk label

Use of Disinfection Hierarchy Approach by Other Regulatory Groups

- ▶ Use by international regulatory groups:
 - ▶ European Union (uses representative organisms and allows non-enveloped virus data to support virucidal claims)
- ▶ Use by other Federal agencies:
 - ▶ FDA (uses representative organisms to support certain disinfectant claims)