U.S Environmental Protection Agency – Office of Pesticide Programs

Exploration of the Disinfection Hierarchy Stakeholder Workshop

Potomac Yard - 1st Floor Conference Room S-1206
2777 South Crystal Drive
Arlington, VA 22202

October 7, 2015

PURPOSE AND FORMAT

The U.S Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) is considering expanding its use of disinfection hierarchy concepts for use in registering antimicrobial pesticide products and is seeking input on options that can be supported by current science and on what scientific issues to consider as limiting factors in the use of a disinfection hierarchy. OPP's main goals for expanding the use of disinfection hierarchy concepts are to: (a) provide more expedient 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 and (b) increase the efficiency of and lower costs associated with registering antimicrobial pesticides while maintaining a high level of public health protection.

Purpose of the Workshop: Provide a forum for scientific experts and stakeholders to discuss: (a) the current science on which the disinfection hierarchy concept is based; (b) scientific issues that may present challenges for its use registering antimicrobial pesticide products, and (c) ideas on how to address these issues. Stakeholders will be given an opportunity to share perspectives on the advantages of expanding the use of disinfection hierarchy concepts for regulatory purposes and the scientific or policy issues EPA should consider.

Workshop Format: A panel of approximately 10-15 experts from a variety of stakeholder perspectives will be invited to discuss a series of charge questions. At the end of each agenda item, time will be provided for questions or comments from the audience. This is an open meeting, subject to space availability. An opportunity to participate by webinar also will be provided. Advance registration is required.

PROPOSED AGENDA

Welcome, Introductions and Agenda (8:30-8:50)

Jack Housenger, Director, Office of Pesticide Programs, USEPA

Gail Bingham, President Emeritus, RESOLVE (facilitator)

Session 1 – *Overview* (8:50-10:15)

Goal: Review key disinfection hierarchy concepts and models and their current use in registering antimicrobial pesticide products.

Presentations [20 min each]

Overview of Current Disinfection Hierarchy Models

Dr. William A. Rutala, *Director, Hospital Epidemiology, Occupational Health and Safety Program, University of North Carolina [invited]*

Overview of Current Use of Hierarchies for Regulatory Purposes

Mark Perry, Leader, Efficacy Evaluation Team, Antimicrobials Division, Office of Pesticide Programs, USEPA

Panel Discussion [30 min]

Audience Questions and Comments [15 min]

BREAK (10:15-10:35)

Session 2 (10:35-12:15) – Variables Affecting the Reliability of Utilizing Hierarchy Concepts

Goal: Identify potential variables that might affect the hierarchical order and, thus, the stability of the hierarchy and reliability of representative organisms under different conditions.

Panel Discussion [85 min]

Charge Questions:

- Which variables have the greatest impact on the stability of the hierarchy? To what degree does this vary between classes of microorganisms?
 - o Physical parameters (pH, temperature, soil load, surface type, etc.)
 - o Chemical parameters (active ingredient(s), formulation, surfactants, etc.)
 - Method variability
- What options might be considered for addressing variables that have an impact on the stability of the hierarchy?

Audience Questions and Comments [15 min]

LUNCH (12:15-1:15) lunch can be brought back to the meeting room

Session 3 (1:15-2:45) – *Selection of Representative Microorganisms*

Goal: Discuss the selection of representative microorganisms within a class of microorganisms.

Panel Discussion [75 min]

Charge Questions:

- What are the relevant characteristics of the microorganisms to consider in determining the most appropriate test organisms to represent all pathogenic organisms within a class?
- In what classes does the science suggest that more than one representative organism may be needed? For which other class(es) of microorganisms is there sufficient information to identify a representative microorganism that reliably meets all the relevant characteristics?

Audience Questions and Comments [15 min]

BREAK (2:45-3:15)

Session 4 (3:15-4:15) – Application of the Disinfection Hierarchy

Goal: Discuss ways in which uses of disinfection hierarchy concepts are supported by current science.

Panel Discussion [50 min]

Charge Questions:

- Given current science, in what ways and/or for what classes of microorganisms can disinfection hierarchy concepts be applied sooner rather than later?
- What are important limitations based on current science?

Audience Questions and Comments [10 min]

Session 5 (4:15-4:55) - Next Steps/Path Forward

Goal: Identify information gaps and other stakeholder perspectives for EPA to consider.

- What data and/or scientific studies could be completed relatively quickly, which could support additional application of the disinfection hierarchy and in what ways?
- What other scientific or policy considerations should EPA take into account in considering expanded use of the disinfection hierarchy for regulatory purposes.

Wrap up comments from the Panel [20 min]

Audience Comments [20 min]

Meeting Wrap-up (4:55-5:00)