Twelfth Antimicrobial Workshop

June 7-8, 2018

Renaissance Arlington Capital View Hotel
2800 South Potomac Avenue
Arlington, VA 22202

Day One—June 7, 2018

7:30 a.m. – 8:30 a.m.  Registration and Continental Breakfast

8:30 a.m. – 8:45 a.m.  Welcoming Remarks

Moderator Day One:  Rhonda Jones, President, Scientific and Regulatory Consultants, Inc.

8:45 a.m. – 9:00 a.m.  Antimicrobial Division:  Current Activities and Future Directions

Anita Pease, Acting Director, Antimicrobials Division, EPA Office of Pesticide Programs (OPP)

9:00 a.m. – 9:45 a.m.  Reregistration and Registration Review

Reregistration and Registration Review are EPA’s hallmark programs designed to ensure that pesticides, including antimicrobials, continue to meet FIFRA standards for registration. This session will provide an overview and update of these Agency programs, including the status and schedule for implementation, along with a discussion of REDs and DCIs.

Richard Fehir, Reevaluation Team Leader, Antimicrobials Division, EPA OPP
Tony Herber, Scientific and Regulatory Consultants

9:45 a.m. – 10:15 a.m.  Update on 810 Product Performance Test Guidelines

Antimicrobial pesticides must have data demonstrating their efficacy against microbial pests such as viruses and bacteria as a precondition to EPA registration. This session will provide attendees with an overview of the recently finalized revisions the Agency’s Series 810 Product Performance Guidelines, which provide recommendations for the design and execution of laboratory studies to evaluate the effectiveness of antimicrobial pesticides that work against public health microbial pests.

Thao Pham, Antimicrobials Division, EPA OPP
Rhonda Jones, President, Scientific and Regulatory Consultants

10:15 a.m. – 10:30 a.m.  Networking Break
10:30 a.m. – 11:00 a.m.  Latest Developments in Disinfectant Claims for Emerging Viral Pathogens

Disinfectant products play a critical role in protecting public health against the increasing number of emerging viral pathogens. However, due to the unpredictability of emerging viral pathogens, few disinfectants have been approved against such viruses, thereby limiting the public’s access to effective products. That is until recently. Attendees will learn about the expedited two stage process and the specific conditions under which EPA will allow manufacturers and distributors to make limited claims against emerging viral pathogens that are not listed on their EPA registered disinfectant label.

Kristen Willis, Team Leader Efficacy Evaluation, Antimicrobials Division, EPA OPP
Julie Timberman, Associate Research Fellow, The Clorox Company

11:00 a.m. – 11:30 a.m.  Status of the SmartLabel Pilot Program

In an effort to make pesticide label information easier to find and the approval of pesticide labels more efficient, EPA is working with pesticide registrants to pilot an electronic label system. This session will provide an overview of the Pilot and an update on its status, which has now entered Phase 3 of the Pilot. In addition, this session will also provide an update on the eCSF application process.

Patricia Parrott, Special Assistant to the Director, EPA OPP

11:30 a.m. – 12:00 p.m.  Updates to the Electronic Submission Portal and CDX

EPA continues to update and expand the Pesticide Submission Portal. This session will address recent additions including the new “Voluntary Submission” link on the PSP home page that allows users to submit study citations, Form 8570-35 data matrices, submission cover letters, and studies including protocols, study profiles, and supplemental study data.

Jose Gayoso, Senior Regulatory Advisor, Antimicrobials Division, EPA OPP

12:00 p.m. – 1:30 p.m.  Networking Lunch

Speaker:  Arnold Layne, Deputy Office Director, EPA OPP

1:30 p.m. – 2:00 p.m.  Antimicrobial Testing Program: Status and Update

Under the Antimicrobial Testing Program, the Agency tests samples of EPA-approved hospital disinfectants and tuberculocides in the marketplace to ensure that the products continue to meet stringent efficacy standards. This session will discuss the status of the program as well as provide an update on ATP, including the critical role it plays in enforcement at the state and federal levels.
Zeno Bain, Team Leader, Antimicrobials Division, EPA OPP

2:00 p.m. – 2:30 p.m.  Pilot Program to Reduce Animal Testing

Learn the latest about EPA’s initiative to develop non-animal alternatives for testing of acute oral, dermal, inhalation toxicity, along with skin and eye irritation and skin sensitization (i.e., the “six-pack” studies), including its pilot program designed to evaluate the usefulness and acceptability of a mathematical tool (the GHS Mixture Equation).

Anna Lowit, Senior Science Advisor, EPA OPP
Eric Ditzel, Regulatory Specialist, Ecolab, Inc.

2:30 p.m. – 3:00 p.m.  EPA Policy on Antimicrobial Devices

In recent years, we have seen growth and innovation in “devices” with antimicrobial properties. These devices include “engineered water”, UV systems for institutional use, and a host of other such products. This session will provide attendees with insight as to how EPA regulates such products, and the process that the Agency has developed to guide its decisions, including its newly formed Devices Workgroup.

Rose Kypriano, Branch Chief, Antimicrobials Division, EPA OPP

3:00 p.m. – 3:15 p.m.  Networking Break

3:15 p.m. – 4:00 p.m.  Review of New FDA Regulations for Antibacterial Washes and Rubs, and Healthcare Antiseptics

Attendees will receive the latest information on the FDA final rule that, effective September 6, 2017, bans triclosan and 18 other active ingredients from use in antibacterial washes intended to be used with water, and how that will impact the marketplace. In addition, attendees will learn about FDA’s recently released regulation that impacts healthcare antiseptics as well as a review of the contemplated regulations that will impact antibacterial rubs, such as hand sanitizers, that rely on certain active ingredients of concern to the agency.

Dr. Om Singh, Senior Scientific Consultant, TSG Consulting

4:00 p.m. – 4:45 p.m.  PRN 2017-XX: Notifications, Non-Notifications and Minor Formulation Amendments and Retailer and State Ingredient Disclosure Initiatives

On September 6, 2017, the U.S. Environmental Protection Agency (EPA) published a notice in the Federal Register announcing the availability of and seeking public comment on draft guidance, Pesticide Registration Notice (PR Notice) 2017-XX: Notifications, Non-notifications and Minor Formulation Amendments. EPA stated it is issuing this notice to “align the notification program with the requirements of the Food Quality Protection Act (FQPA) and [the Pesticide Registration Improvement Act (PRIA)] and to clarify the processes for accepting
minor, low risk registration amendments to be accomplished through notification, non-notification or as accelerated amendments.” It will replace past guidance issued as PR Notice 98-10. This session will provide an overview of the proposed changes as well as a summary of suggestions offered in the public comments. Of particular interest, the Agency requested feedback on a process for ingredient disclosure information. The industry perspective on the process and the collaborative effort between industry, retailers and EPA will be discussed.

Jim Jones, EVP, Strategic Alliances & Industry Relations, HCPA
Bill McCormick, Research Fellow, Global Stewardship & Innovation, The Clorox Company

4:45 p.m. – 5:30 p.m. EPA/FDA Dual Jurisdiction: Food Use & Medical Devices

Depending on their intended use, antimicrobial pesticides may come under the jurisdiction of EPA, FDA or both. This session will address antimicrobial food uses that are regulated solely by FDA as well as those regulated by both agencies. In addition, jurisdictional issues related to antimicrobial pesticides intended for use on medical devices will be explored.

Office of General Counsel, U.S. Environmental Protection Agency
Elise N. Paeffgen, Senior Associate, Alston & Bird

5:30 p.m. – 7:00 p.m. Networking Reception

7:00 p.m. - TBD Dinner on Your Own

Day Two—June 8, 2018

7:30 a.m. – 8:30 a.m. Continental Breakfast

8:30 a.m. – 8:45 a.m. Welcoming Remarks

Moderator Day Two: Diane Boesenberg, Manager of Regulatory Affairs, Reckitt Benckiser

8:45 a.m. – 9:30 a.m. Update on the EU’s Biocidal Products Regulation

The Biocidal Products Regulation has been in effect since September 2013, and has significantly changed the way biocidal products are regulated in the European Union. Attendees will receive an update on this important set of regulations that ultimately determine what biocidal products may be placed on the European market.

Seth Goldberg, Steptoe & Johnson LLP
Darren Abrahams, Steptoe & Johnson LLP
9:30 a.m. – 10:00 a.m.  K-BPR: South Korean Act on Chemical Consumer Products and Biocides

On August 8, 2017, South Korea proposed a new biocides law, the Act on Chemical Consumer Products and Biocides (K-BPR), modeled after Europe’s BPR. If passed, the law will become effective January 1, 2019. Attendees will be provided with an overview of K-BPR with a special focus on the pre-approval system for all biocidal substances and products.

Robert Kiefer, General Manager & President, REACH24H Consulting Group

10:00 a.m. – 10:15 a.m.  Networking Break

10:15 a.m. – 11:00 a.m.  China: Disinfection Product Regulations

The China Disinfection Product Regulations were reformed at the end of 2014, and are now in effect. This session will provide attendees with an overview of the process by which one obtains a “license” to market disinfectant and other antimicrobial pesticides in China.

Nancy Shen, Regulatory Specialist, REACH24H Consulting Group

11:00 a.m. – 11:30 a.m.  Canada: Update on Antimicrobial Policies and Harmonization with U.S. EPA

This session will provide an update on Health Canada’s regulation of disinfectants and sanitizers, as well as review ongoing efforts to harmonize the registration requirements between those of the U.S. and Canada. This session will also address the priorities of the Natural and Non-Prescription Health Products Directorate (NNHPD) as it relates to the regulation of disinfectants.

Heather Barker, Director of Government and Regulatory Affairs, Reckitt Benckiser

11:30 a.m. – 12:00 p.m.  NAFTA Renegotiations: Implications for the Antimicrobial Industry

The topic of NAFTA renegotiations raises a wide range of environmental concerns as well as an even broader range of public interest and economic issues. Attend this session and learn what implications the NAFTA renegotiations have for the antimicrobial industry.

Speaker to be determined.

12:00 p.m. – 1:30 p.m.  Networking Lunch

Speaker to be determined.
1:30 p.m. – 2:00 p.m.  Update on U.S. EPA DfE Pilot Program for Disinfectants

In addition to the EPA Safer Choice label, EPA offers the Design for the Environment (DfE) option for use on disinfectants and sanitizers under its antimicrobial pesticide pilot project. This session will provide the latest information on this unique pilot that has been extended to May 2018.

Clive Davies, Chief, Design for the Environment Branch, EPA Office of Pollution Prevention and Toxics
Jacqueline Hardy, Team Leader, Antimicrobials Division, EPA OPP

2:00 p.m. – 2:45 p.m.  Update on the Antimicrobial Exposure Assessment Task Force (AEATF II)

The Biocides Panel of the American Chemistry Council established an Antimicrobial Exposure Assessment Task Force II (AEATF II) the goal of which is to conduct human exposure monitoring studies involving the mixing, loading, and application of products containing antimicrobials. This effort is focused on meeting the EPA re-registration and registration review data requirements for antimicrobial active ingredients as well as to support new active ingredient registration applications. Learn about the latest developments of the AEATF II to support antimicrobial registrations.

Timothy Leighton, Antimicrobials Division, EPA OPP
Has Shah, American Chemistry Council
Bill Goodwine, Senior Director of Regulatory Affairs and Risk Assessment, Janssen PMP

2:45 p.m. – 3:30 p.m.  State Regulatory Issues: Minimum Risk Pesticides and FIFRA §25b Products

Erica Millette, Program Director, New Mexico Department of Agriculture

3:30 p.m. – 3:45 p.m.  Discussion and Overview of Twelfth Antimicrobial Workshop

Rhonda Jones, President, Scientific and Regulatory Consultants, Inc.
Diane Boesenberg, Manager of Regulatory Affairs, Reckitt Benckiser

3:45 p.m.  Adjourn

*Agenda is preliminary and subject to change*