December 31, 2019

Kristen Willis
Branch Chief, Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: EPA–HQ–OPP–2018–0265; Antimicrobial Performance Evaluation Program (APEP): Draft Risk-Based Strategy to Ensure the Effectiveness of Hospital-Level Disinfectants; Notice of Availability and Request for Comments

Dear Ms. Willis:

The Association for Professionals in Infection Control and Epidemiology (APIC) welcomes the opportunity to comment on the topic of the Antimicrobial Performance Evaluation Program (APEP): Draft Risk-Based Strategy to Ensure the Effectiveness of Hospital-Level Disinfectants. APIC is a nonprofit, multidisciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection. It is concerning that more than one-third of tested hospital disinfectants failed efficacy testing. We are pleased that the U.S. Environmental Protection Agency (EPA) has welcomed public input on the topic of the effectiveness of hospital-level disinfectants. This issue is pertinent to our organization’s mission and vision of healthcare without infection, and we are responding to share our concerns and provide input to facilitate your decision-making process.

EPA Focus Questions

1. Please comment on the proposed risk factors and refinements, their proposed prioritization, their strengths and limitations, and recommendations for other risk factors not considered.

APIC supports the concept of a “roadmap” to identify several risk factors for product testing under APEP. APIC agrees with the EPA-established testing priority, including testing for Gram-positive organisms, Gram-negative organisms, spore-forming C. difficile (also a proxy for Candida auris), influenza (a representative enveloped virus) and norovirus (a representative non-enveloped virus) and M. tuberculosis. However, APIC strongly recommends inclusion of an additional enveloped virus (e.g., hepatitis B virus), a bloodborne pathogen, to support compliance with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard 29 CFR 1910.1030(d)(4)(iii)(A), as it relates to decontamination of work surfaces. APIC also recommends inclusion of a non-enveloped
virus (e.g., coxsackieviruses, rotavirus, poliovirus, adenovirus and/or hepatitis A), as norovirus is one of few non-enveloped viruses with a particularly complex capsid enclosure that makes it more resistant to disinfectants than most non-enveloped viruses.\textsuperscript{2, 3} APIC suggests consideration for removal of Methicillin-resistant \textit{Staphylococcus aureus} (MRSA) from priority testing, as the CDC identifies that disinfectants effective against \textit{Staphylococcus aureus}, or staph, are also effective against MRSA.\textsuperscript{4} Additionally, APIC would like to place significant emphasis on the critical factor of the product’s contact time, as addressed in line 357 of the EPA draft risk strategy,\textsuperscript{5} as it pertains to the second risk factor.

APIC agrees that the most important risk factor for the product selection process is the consideration of the microbial species, in conjunction with disease prevalence data. We also recognize and support compliance with the OSHA Bloodborne Pathogens Standard 29 CFR 1910.1030(d)(4)(ii)(A) as it relates to cleaning and disinfection. We support prioritization of efficacy evaluation for disinfectants with claims to control specific microbes deemed critical to public health. We strongly support the use of published data and information to identify factors that facilitate surface-mediated transmission of pathogens with prioritization of those. According to the 2019 CDC Antibiotic Resistance Threats Report, more than 2.8 million antibiotic-resistant infections occur in the U.S. each year, and more than 35,000 people die as a result.\textsuperscript{6} As described in line 291 of the EPA draft risk strategy, “These microbe specific factors include environmental persistence, frequency of occurrence on clinical surfaces, ability to colonize hands of healthcare workers, ability to colonize patients, and a low inoculating dose;”\textsuperscript{7} all factors that contribute to the CDC 2015 estimates of 687,000 healthcare-associated infections in U.S. acute care hospitals.\textsuperscript{8} Appropriate use of an EPA-registered hospital disinfectant is one way that healthcare personnel can “break the chain of infection.” Using effective cleaning and disinfection agents, both the infectious agent(s) and reservoirs can be eliminated, greatly reducing morbidity and mortality of healthcare consumers.\textsuperscript{9}

APIC recognizes two additional risk factors regarding disinfectants:

a. Compatibility of the disinfectant with common healthcare surfaces, instruments, and devices.

b. Safety and ease-of-use for the humans utilizing the products.

While these risk factors are unrelated to disinfectant label-claims, APIC encourages the EPA to consider these items when approving disinfectants. Both are often barriers to appropriate disinfection within healthcare facilities. Although EPA’s jurisdiction is limited to the efficacy of the disinfectant itself, the manufacturers’ instructions for use are also an essential component in the overall goal of preventing the spread of infection to ensure the safety of patients and healthcare personnel. Healthcare facilities rely on the consistency of guidance from all federal agencies with jurisdiction over environmental disinfection – including EPA, OSHA, CDC, and the Food and Drug Administration – to ensure the most effective and safe care of patients.
3. **Should the Agency and/or stakeholders conduct the laboratory evaluation (formulation chemistry and product efficacy) of disinfectant products? Provide examples to support your opinions and itemize situations where one approach would be more favorable versus the other.**

APIC has read and considered the proposed laboratory options for evaluation of efficacy and formulation testing. We suggest separation of options for formulation chemistry versus product efficacy to avoid bias. In a scenario where a manufacturer has already placed a label claim, pressure to validate the label claim exists. If separation is not feasible retention of the language on line 514 of the EPA draft risk strategy, “Under this option, EPA retains discretion to have the Office of Pesticide Programs (OPP) Analytical Chemistry Branch (ACB), OPP Microbiology Laboratory Branch (MLB), a laboratory with an interagency agreement or contracted by EPA to verify the validity of chemistry and/or efficacy results submitted by the registrant as determined necessary by the Agency” is strongly encouraged.

4. **Please comment on the flexibility and feasibility of the example workplan approach (See Appendix A, draft Strategy).**

APIC agrees with the proposed workplan, including the timeline and proposal of *C. difficile* as the first initiative under APEP. According to the 2019 CDC Antibiotic Resistance Threats Report, *C. difficile* is identified as an urgent threat responsible for an estimated 223,900 cases in hospitalized patients, 12,800 deaths, and $1 billion in healthcare costs for 2017 alone. Likewise, *Candida auris* has been identified an urgent threat. With *C. difficile* acting as the proxy for *Candida auris*, healthcare facilities will have validation of product effectiveness for two urgent threats.

5. **Please comment on the proposed communication strategy to convey test results to registrants and the general public including the preferred frequency of updates.**

APIC agrees with disseminating APEP test results via multiple forms of communication and displaying summary tables to assist consumers in making informed choices regarding infection prevention and control in their facilities. CDC has identified environmental cleaning and disinfection as one of the core infection prevention and control practices for safe healthcare delivery in all settings. Emphasis on selecting EPA-registered disinfectants that have microbiocidal activity against the pathogens most likely to contaminate the patient-care environment and following manufacturers’ instructions for use are identified as core practices. Once results have been finalized (i.e., EPA Biological Report of Analysis), these results should be retrievable from the summary table. APIC encourages responsibility from the registrant to inform consumers and regulatory agencies of the APEP results on their website and ideally active outreach (similar to a recall notification). For example, once all registrants with *C. difficile* claims have undergone testing and have results, there should be clear expectations of how the public is notified in a timely manner, particularly for the products that are not effective. Expedient notification is integral to preventing active spread of infections in the interim. In addition, frequent updates to the EPA Pesticide
Registration Selected EPA-registered Disinfectants site will ensure healthcare facilities select the most efficacious disinfectant. The current List K: EPA’s Registered Antimicrobial Products Effective against *Clostridium difficile* Spores was last updated on January 10, 2018.

6. **Please provide suggested routes for resolution of efficacy failures. Previously, these were addressed by “regulatory fixes” to include retesting, label amendments, etc.**

APIC agrees with retesting and label amendments. We recommend required notification to customers, as opposed to only “regulatory fixes”. It is imperative that the customers (healthcare facilities) understand the efficacy of the disinfectants they are using to ensure a safe patient care environment.

APIC again thanks EPA for the opportunity to provide comments on the draft strategy, and we look forward to continuing to work with the agency to prevent the spread of infection in healthcare facilities.

Sincerely,

Karen Hoffmann, RN, MS, CIC, FSHEA, FAPIC
2019 APIC President


12 Ibid. (12)