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Ms. Kathryn Montague
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW.
Washington, DC 20460-0001

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U.S. Environmental Protection Agency
Mailcode: 28221T
1200 Pennsylvania Ave. NW.
Washington, DC 20460

Re: Docket ID No: EPA-HQ-OPP-2018-0265

Thank you for the opportunity to comment on the, "Antimicrobial Performance Evaluation Program – Development of a Risk-Based Strategy". This draft Strategy was developed by the EPA Office of Chemical Safety and Pollution Prevention (OCSPP) in response to the EPA Office of Inspector General (OIG) report titled: "EPA Needs a Risk-Based Strategy to Assured Continued Effectiveness of Hospital-Level Disinfectants." The draft Strategy provides a framework to ensure that **registered** hospital-level disinfectants and tuberculocide products continue to meet Agency efficacy standards once they are in the marketplace.

This letter is in regard to the draft Strategy and related issues and is submitted on behalf of the members of the Association of American Pesticide Control Officials (AAPCO). The Association of American Pesticide Control Officials (AAPCO) was formed in 1947, the same year that Congress enacted the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). AAPCO members represent the officials charged by law with the execution of the state, territorial, provincial, and federal laws in the United States, including all its territories, and in Canada regulating the production, labeling, distribution, sale, use, and disposal of pesticides. Pesticides regulated by AAPCO members include antimicrobial pesticides which are public health products, that are intended to control microorganisms infectious to humans in any inanimate environment.

AAPCO has reviewed the ***Antimicrobial Performance Evaluation Program – Development of a Risk-Based Strategy to Ensure the Effectiveness of Hospital-Level Disinfectants***. We applaud EPA’s efforts in developing a more risk-based strategy for “ensuring the effectiveness of hospital-level disinfectants” and protecting human health. Our members, as well as EPA, strive to protect human health and the environment in our various regulatory programs, through our monitoring of pesticidal products in the channels of trade including the end user level, including hospitals, nursing homes, nurseries, and child care facilities, to name a few affected by antimicrobial products.

We have no adverse comments to the proposed Strategy. We are particularly appreciative of the recognition that, “Cleaning, along with treatment of inanimate environmental surfaces, with EPA-registered hospital level disinfectants is a component of standard infection practices used to interrupt and mitigate the transmission of pathogens associated with healthcare associated infections.”

Concerns About Lack of Adequate Oversight

AAPCO is concerned about an alarming shift in practices implemented by health care facilities who are using non-government evaluated pesticide devices that make unsubstantiated human health claims, including the control of certain pathogenic bacteria, fungi, and spores. The devices are being used in a variety of facilities and industries and may produce substances such as electrolyzed water, hypochlorous acid, ozone, and chlorine dioxide touted for disinfecting, sanitizing and sterilizing hard surfaces. Ultraviolet lighting is also being sold for use for sanitation purposes to these facilities.

AAPCO recognizes that in some instances, it may be appropriate to exempt devices from pesticide registration. However, when these devices produce substances that provide pesticidal claims similar to “...environmental cleaning and disinfecting that aims at reducing harm to human health and the environment...”, they have entered an area outside the normal realm of devices used to destroy, repel, trap or mitigate any pest. These devices are often generating active ingredients and making human health claims, similar to EPA-registered Section 3 products.

Our biggest concern is the use of these devices in establishments such as hospitals, nursing homes, and childcare facilities, with no scientific data being submitted to EPA to prove their effectiveness in reducing harmful bacteria, fungi or other disease-causing pathogens. Furthermore, the thought of a hospital, nursing home, or childcare facility using these products instead of hospital-grade, EPA-registered antimicrobial products is alarming. Those products must submit the testing protocols for registration and prove effectiveness in control

of *Staphylococcus aureus* (*S. aureus*) and *Pseudomonas aeruginosa* (*P. aeruginosa*). In addition, it is unknown whether these devices, which may be producing sublethal amounts of a toxicant, are contributing to the rise of infection rates in some health care facilities. With the increasing incidence of drug-resistant pathogens, it is even more critical to ensure that disinfection and sanitation products and procedures are reliable, tested and effective.

As a means of protecting public health, AAPCO members are often involved with inspections and investigations. Staff from the North Carolina Department of Agriculture and Consumer Services have identified two hospitals that utilize a hypochlorous acid generator (a type of device) for sanitation purposes. Upon inspection, they found that the hypochlorous acid generator is the sole disinfectant used by the facility. The generators produce three different concentrations of available chlorine depending on the level of sanitation needed. Hospital officials are convinced that the control provided by the devices is adequate and exceed levels provided by hospital-grade disinfectants. If we fail to bring this issue forward, we are not doing our part to protect the human health of our citizens, and we think EPA must be equally concerned.

The webpages for these various devices are touting pesticidal claims such as “proven effective on biofilm, viruses, bacteria such as *E. Coli*, *Clostridium Difficile*, and *Staphylococcus aureus*, fungi and algae, with the benefits of no buildup of resistance, reduced costs, greatly reduces use of conventional agents, green, safe and easy to use with on-site production.” These claims are made without adequately reviewed data which prove efficacy or otherwise support these antimicrobial claims against organisms of significant public health concern.

To further confuse the users of these generators, many companies with these generators also produce pesticides for distribution with the same active ingredients as those substances being produced by the generators. Much of the literature associated with the generators is woefully inadequate in providing any meaningful reviewed data. In addition, these devices and the associated sales literature may also be a form of misbranding because of claims of being a “US EPA Registered Sterilant”, inaccurate citing of EPA Est. No. with product registration numbers, and other misleading statements.

According to current EPA enforcement opinion, these hypochlorous acid generators are considered to be devices, if the companies providing the generators do not supply all the components needed for the generation of hypochlorous acid. For instance, if the hospital provides the salt, like one would buy at large format retailers, then the hypochlorous acid generators would be considered a device. However, if the companies providing the generators supply all the components needed for the generation of hypochlorous acid, then it falls under the

definition of a pesticide. This is a loophole that is potentially impacting human health and safety.

EPA's Role in Protecting Public Health

FIFRA defines:

- A pesticide as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.”
- A “device” as any instrument or contrivance (other than a firearm) that is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism **on or** in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

According to EPA:

- Devices can be intended for use on both conventional and antimicrobial pests.
- The Antimicrobials Division receives the majority of device determination inquiries.
- Because these products are not registered as pesticides, neither efficacy claims nor device safety are reviewed by EPA.
- Many devices being sold make public health claims. Companies cannot make false or misleading claims on their product labels and they must be able to substantiate any pesticidal claims.
- A device must work only by physical means (such as electricity, light or mechanics), e.g., antimicrobial UV lights, bird-repellent sonic cannons and filters using only mechanical means.
- A device must not incorporate (or be sold with) a substance or mixture of substances to perform its intended pesticidal purpose.

Request

AAPCO encourages EPA to require:

- Data to substantiate any health-based pesticidal claims and regulate companies that make false or misleading claims on their product labeling.
- Registration as a pesticide if a pesticide substance is being produced by the device, and the device does not work only by physical means (such as electricity, light or mechanics).

AAPCO appreciates EPA's recognition that the proper use of efficacious disinfectant products plays a vital role in protecting human health; and the unique and critical role and responsibility that the agency has in ensuring that these products are properly evaluated and registered.

We encourage EPA to further refine the definition of devices and require pesticide registration for generators that produce a substance that acts as a pesticide. EPA should also begin to evaluate these products for proven effectiveness, especially for those products making human health claims.

This letter was developed with significant contributions from James Burnette (former AAPCO President) and Patrick Jones (AAPCO Board of Directors), both from the North Carolina Dept. of Agriculture and Consumer Services.

Sincerely,



Rose Kachadoorian
AAPCO President
Pesticides Program Manager,
Registration, Licensing and Certification
Natural Resource Policy Area
Oregon Department of Agriculture
635 Capitol Street NE, Salem, Oregon 97301
Phone: (503) 986-4651
[Email: rkachadoorian@oda.state.or.us](mailto:rkachadoorian@oda.state.or.us)