ISSUE PAPER
Pesticide Devices Making Public Health Claims
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The North Carolina Department of Agriculture and Consumer Services has always taken its core mission of protecting human health very seriously, in as much we have sampled and conducted microbiology performance testing of registered antimicrobial products for many years. We are alarmed by some recent shifts in pesticide devices that make public health claims. 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[1], sanitizing[2] and sterilizing hard surfaces. Ultraviolet lighting is also being sold for use for sanitization and disinfection purposes in these facilities.

We do understand and support many devices being exempt from pesticide registration, but when these devices produce substances that declare 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 traditional realm of devices used to destroy, repel, trap or mitigate any pest. These devices are extending into areas similar to EPA registered FIFRA Section 3 products that make public health claims.

Our biggest concern is the use of these devices in establishments such as hospitals, nursing homes, child care facilities, food processing, livestock, cruise ships, and fresh fruit and vegetable processing, with no scientific data being submitted to EPA to prove their effectiveness in reducing bacteria, fungi or other disease-causing pathogens. Furthermore, the thought of a hospital, nursing home, or childcare facility using these products instead of EPA-registered antimicrobial products is alarming. EPA-registered products must submit the efficacy testing for registration to prove effectiveness in control of *Staphylococcus aureus* (*S. aureus*) and *Pseudomonas aeruginosa* (*P. aeruginosa*).

We have two hospitals in NC that utilize a hypochlorous acid generator for sanitation purposes. Upon inspection we 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 sanitization or disinfection 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 human health to our citizens in NC, 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”. All these claims are made without validated data to 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. Some of the literature is woefully inadequate to provide any data and is also considered to be misbranded because of claims of being a “US EPA Registered Sterilant”, inaccurate citing of EPA Est. No. with product registration numbers, and other misleading statements. There are few products that are registered as sterilants. A sterilant, per 40 CFR 158.2203, must destroy or eliminate all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses.

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

- EPA develop a document providing guidelines and acceptable claims on devices, particularly devices associated with public health claims.
- EPA require the manufacture/registrant to provide data to substantiate any public health pesticidal claims and regulate companies that make false or misleading claims on their product labeling.
- EPA require registration of a device 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).
- Devices which generate different types of pesticidal substances may be used in a wide variety of enclosed spaces, such as health care facilities, schools, or greenhouses. The types of pesticides include but are not limited to: antimicrobials, insecticides, and fungicides. It is requested that EPA develop standards to ensure the safety of pesticide handlers, workers and other persons which may use devices or entered treated spaces.

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.

[1] **Disinfectant**: a substance, or mixture of substances that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment.

[2] **Sanitizer**: a substance, or mixture of substances, that reduces the bacterial population in the inanimate environment by significant numbers, (e.g., 3 log10 reduction or more), but does not destroy or eliminate all bacteria. Sanitizers meeting Public Health Ordinances may be used on food contact surfaces and are termed sanitizing.