

in focus

Pesticidal
Devices -
Validating
their efficacy



The advent of the Covid-19 pandemic has brought a renewed focus on monitoring standards of cleanliness. A new breed of product – pesticidal devices – is hitting the market in the US and includes items such as UV or ozone disinfection devices. Despite the significance of this type of product, they are largely unregulated at the federal or state level. This makes it difficult for consumers to choose between effective and ineffective devices and hence for manufacturers to differentiate their products. Manufacturers can, however, make claims about the efficacy of their products and these claims are subject to regulatory oversight. This paper discusses what to consider when making claims about your product and the information you will need in order to substantiate them.



The importance of disinfection

The transmission of pathogenic bacteria and spores to human skin can occur through touching contaminated surfaces. Many microorganisms, such as coronavirus and influenza viruses can survive on surfaces for days while other microorganisms such as *Clostridioides difficile* and *Staphylococcus aureus*, can survive for weeks or months. Hence, thorough cleaning and disinfection of surfaces is needed to interrupt the environmental transmission of infectious microorganisms to humans.

To supplement standard products such as liquid disinfectants, antimicrobial pesticide devices are becoming widely used across multiple industries.



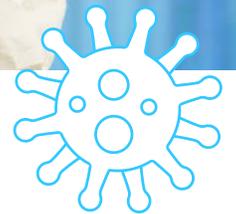
Consumers and organizations are interested in products that disinfect the harder to reach surfaces that standard disinfectants can miss. But how can the disinfection efficacy of different systems be compared?



The regulatory framework

Efficacy validation for traditional liquid disinfectants and pesticidal devices is important for maintaining public health and safety. While disinfectants are regulated and require registration by the Environmental Protection Agency (EPA) and the states, pesticidal devices have little regulatory oversight and not all states require their registration. Although the EPA has no formal registration process for pesticidal devices, it does regulate production, import/export, and product claims. Manufacturers therefore must be able to substantiate the claims they make through efficacy validation data. Antimicrobial pesticide devices are becoming increasingly prevalent on the market, yet we see few efficacy claim disputes by the EPA and how the Agency challenges manufacturers to substantiate them. EPA Administrator Wheeler warned retailers

about potential enforcement actions for products that make false SARS-CoV-2 efficacy claims¹. EPA can issue stop sale orders to remove products making unsubstantiated claims from the market. On October 30, 2020, EPA's Office of Enforcement and Compliance Assurance (OECA) issued a Compliance Advisory document specific to UV devices that make claims to kill viruses and bacteria². The purpose of the document was to provide guidance and clarity associated with the federal requirements associated with the labeling, reporting, sale and distribution of pesticidal devices, namely UV device products.



¹ "EPA Administrator Wheeler Talks with Retailers and Third-Party Marketplace Platforms to Discuss Steps to Protect American Consumers from Fraudulent Coronavirus Disinfectant Claims" EPA.gov, April 3, 2020, <https://www.epa.gov/newsreleases/epa-administrator-wheeler-talks-retailers-and-third-party-marketplace-platforms-discuss>

² "EPA Regulations About UV Lights that Claims to Kill or Be Effective Against Viruses and Bacteria" EPA.gov, October 30, 2020, <https://www.epa.gov/sites/production/files/2020-10/documents/uvlight-complianceadvisory.pdf>

What's in a claim?

Efficacy claims define the product's performance standard against pests; therefore regulatory bodies are concerned with statements such as:

- This water treatment unit kills 99.9% of microorganisms, making water safe to drink
- UV room disinfectant - kills 99.999% of *Clostridioides difficile* on hospital sheets in ten minutes
- Ethylene oxide sterilizer - kills all bacteria on surfaces

These claims relate to different levels of efficacy. The most commonly used antimicrobial products are sanitizers, disinfectants, and sterilants. Sanitizers are used to reduce microorganisms from surfaces. Sanitizers include products that are used to treat food and non-food contact surfaces. Non-food contact sanitizers must reduce 99.9% of bacteria on a surface within 5 minutes.

Disinfectants are used to destroy or inactivate bacteria, viruses, and fungi on treated surfaces. Disinfectants are divided into three groups: limited spectrum, broad spectrum, and hospital disinfectants. These products must demonstrate effectiveness against bacteria at the 95% confidence level (killing 59 out of each set of 60 carriers). Sterilants are the least common antimicrobial pesticide and are used to eliminate all microorganisms from a surface.

These are the performance standards for traditional liquid antimicrobial products. There is no defined performance standard for pesticidal devices. EPA has informally indicated they expect the same level of performance for devices if they want to make the claim on the product label that the device can sterilize, disinfect or sanitize.

In the field of environmental microbiology, efficacy is defined in terms of microbial removal. This is typically expressed in terms of log reduction or % reduction. For example, a 6 log₁₀ reduction, which is the same as a 99.9999% reduction (a 1,000,000 fold reduction), means that roughly only 1 colony forming unit (CFU) of bacteria would remain on the surface. A 3 log₁₀ reduction, which is the same as 99.9% reduction (a 1,000 fold reduction), means that approximately 1,000 CFUs of bacteria would still remain on the surface.



Determining a testing procedure

Because of the diversity of device types, styles, functions as well as emerging new technologies, there are few standardized test protocols for device efficacy testing. A logical first step is to complete field trials as this demonstrates product efficacy to the end user while substantiating claims. However, testing in the field is not the most practical first option because study permissions will generally require approvals from third parties.

For example, prior to on-site testing, an installation agreement would be needed with the facility or hospital where the device will be

tested with explicit permission to bring it in. In many cases, an independent Institutional Review Board (IRB) approval is required. The IRB will review the study purpose and design and will approve or disprove the study based on several factors, including study purpose, ethics, and safety. Further, testing in the controlled environment of a certified laboratory is needed for most regulatory purposes.

It is therefore worth understanding the likely efficacy of your product before moving to field trials.



Protocol development: How do I test my claim?

A good first step to substantiating claims is through laboratory testing. Testing in a controlled laboratory setting is more efficient than, and a recommended step before, field testing. It provides data needed to get agreement from collaborating parties in the field, as well as valid scientific proof for inquiring regulatory bodies. However, laboratory testing requires a testing protocol and manufacturers of new devices on the market can utilize either a modified version of an existing protocol or develop a new one.

It is important to address the four questions below before undertaking laboratory efficacy testing. They help to put the claim into context, as well as highlight the data required to prove it.

1. What is the claim and for whom?

Clearly identify the industry you plan to market (example: healthcare, food industry, consumers) and determine if your claim is one of sanitization or disinfection. This is the most important question as it determines exposure and testing parameters. This question will also help establish your criteria for a successful testing study design.

2. Can any lab perform the testing?

Find a lab that is right for the job. The lab should have experience handling the test microorganisms you are interested in. For example, not all labs can test viruses or mycobacteria. If your device is bulky and/or requires installation in order to be tested, check to make sure that the lab will allow a hook-up to an electrical panel or to a water line in the testing area.

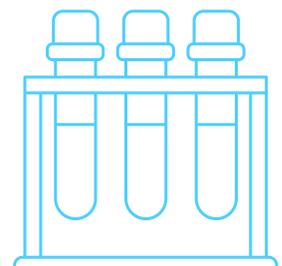
3. What are my exposure parameters?

Exposure parameters include exposure time, temperature, test microorganisms and other characteristics that will vary depending on the technology and on the operation of the device.

4. What are my testing parameters?

Testing parameters include having a proper test vehicle or “carriers” and should represent the product’s instructions for use. For example, if your product is used on surgical equipment, the protocol would want the testing performed on medical grade stainless steel carriers. You will also need to have appropriate positive and negative controls in place as well as an adequate amount of test samples to achieve statistically significant results. A neutralizer is usually needed, so a neutralizer validation should be done beforehand.

Claim substantiation for pesticide devices is critical, however, the lack of established performance criteria and clear regulatory guidance can provide a roadblock for generating data to support efficacy claims made on a product label.



Data! Data! Data!

Product claims are substantiated with data – and the data you need is dictated by the claim to be made. An efficacy claim for an antimicrobial device may require development of a study protocol to be executed in a microbiology laboratory. Therefore, it is important to be smart about what you are trying to validate and to understand the type of data needed for analysis before designing the study.

When designing a study, you should define the parameters of the testing to ensure the appropriate quantitative data will be produced. It is also important to determine how the data will be analyzed prior to testing. This allows for collection of the appropriate data for the desired statistical analysis. If you don't have a scientist as part of your staff, you should hire a specialist to help you understand your testing needs and then develop study protocols to produce the requisite data.

While EPA does not require submission of data for pesticidal devices, EPA will review data for devices making pesticidal claims. This voluntary submission may be made to the EPA's Antimicrobials Division.

A well-designed study protocol is critical to support efficacy claims and will help to reinforce to consumers the performance of the product.



Why is it important to validate the efficacy of devices?

A manufacturer should ensure that their pesticidal device claims are validated for several reasons. First and foremost, validation efforts provide appropriate data to meet state or federal requirements and evidence for truth in claims. The data also provides manufacturers with evidence-based science to present to customers and other stakeholders which builds brand trust.

Scientific data that validates claims can be turned into communication pieces – arming marketing and business development teams for proper advertising and overall positioning in the market. With the right data in hand, companies can confidently communicate a products' unique benefits and value while simultaneously satisfying regulatory needs.



How TSG can help?

TSG's consultants have knowledge of the transmission of pathogens and understand the complexity of how bacterial transmission can occur in various industries. We can assist in developing protocols for decontamination as well as advise our clients on the best practices for disinfection. Our consultants can assist in the development of testing protocols to produce the data needed for validating

efficacy claims. We can also provide guidance and support on general federal and state regulatory requirements associated with pesticide devices, enabling you to meet your compliance objectives and successfully market your product.

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We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry.

This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance. TSG Consulting has offices in France, Germany, Spain, UK, USA and Canada. TSG is a Science Group (London listed) company.

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