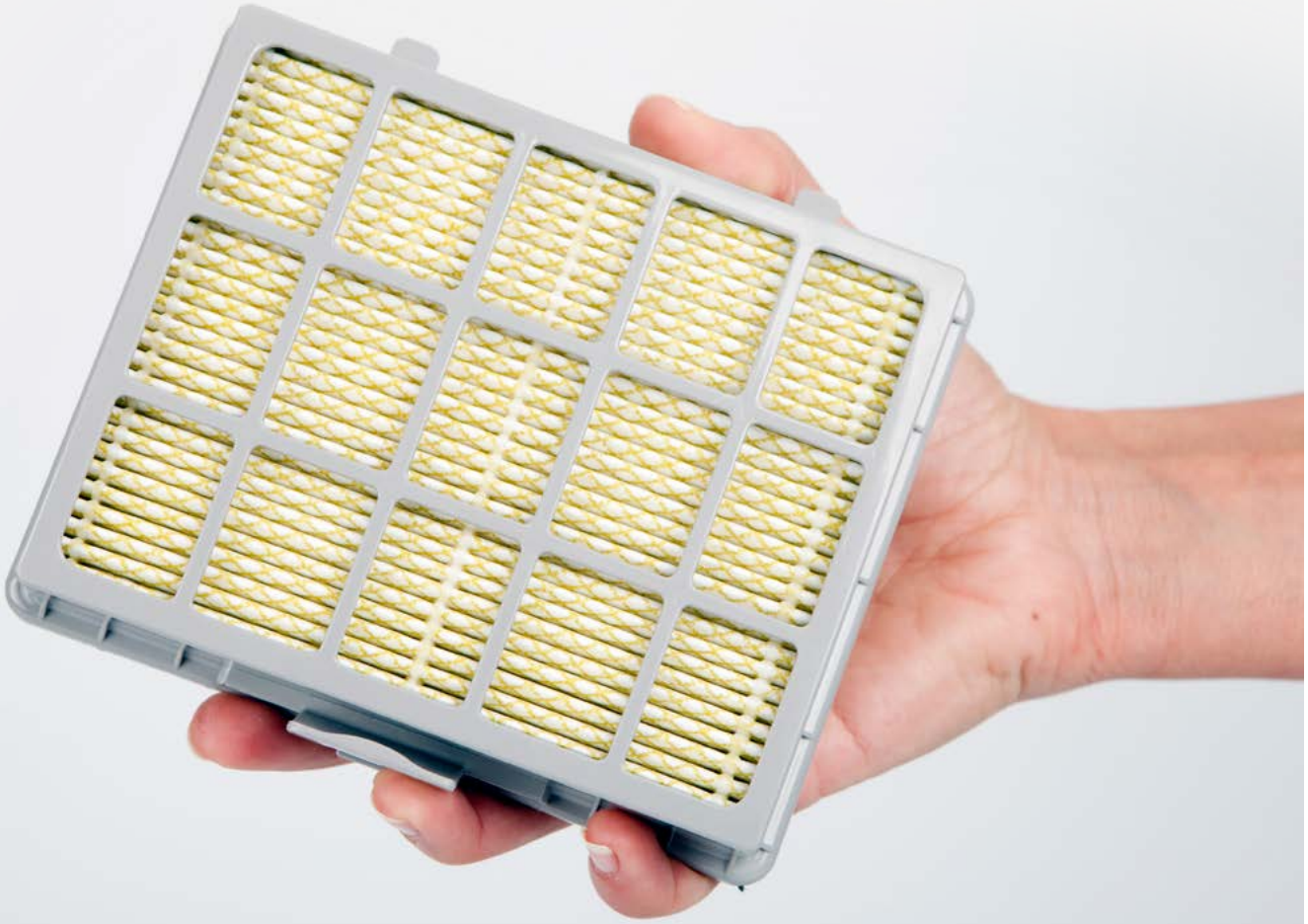
in focus

Pesticide devices
The US regulatory landscape



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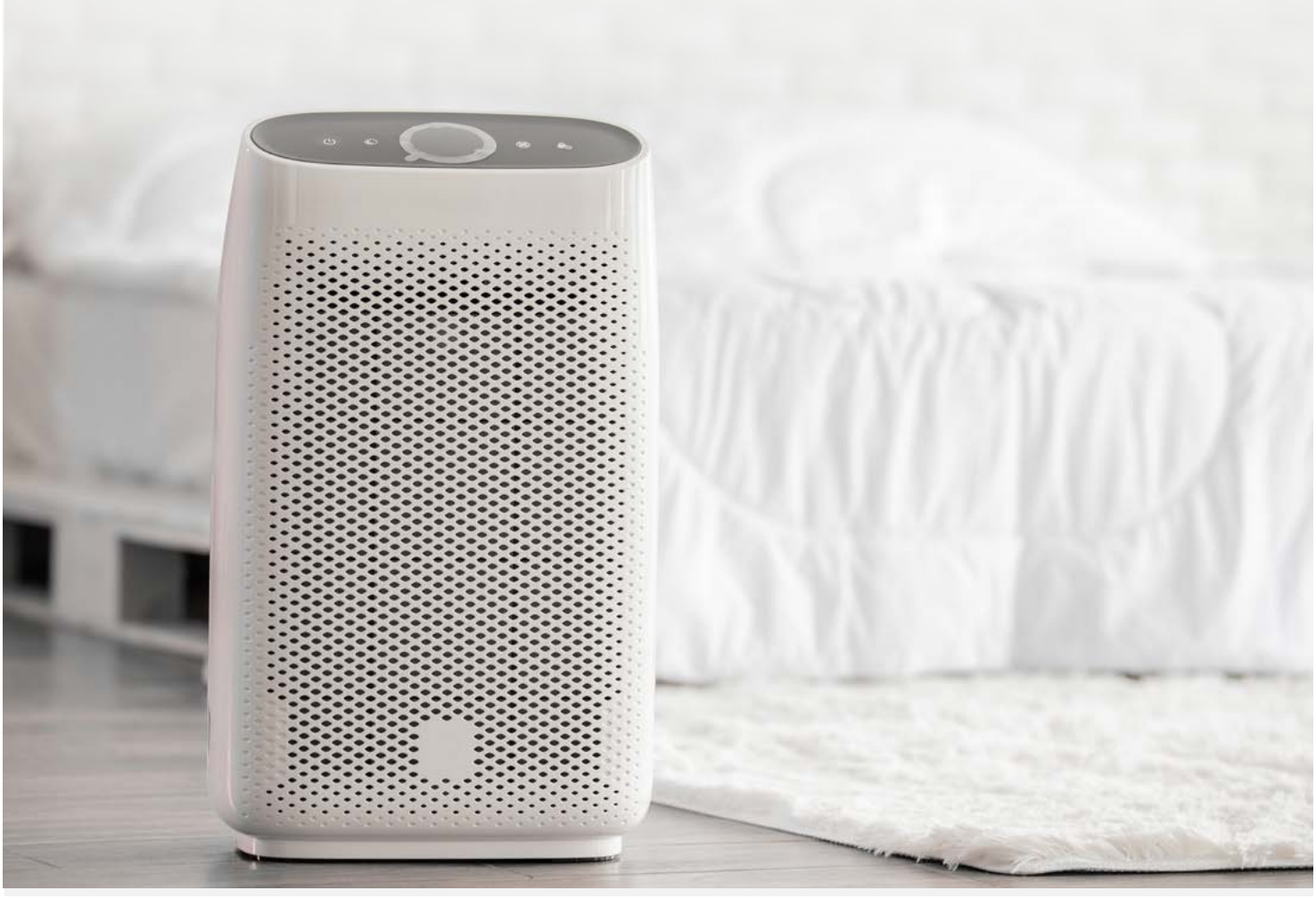
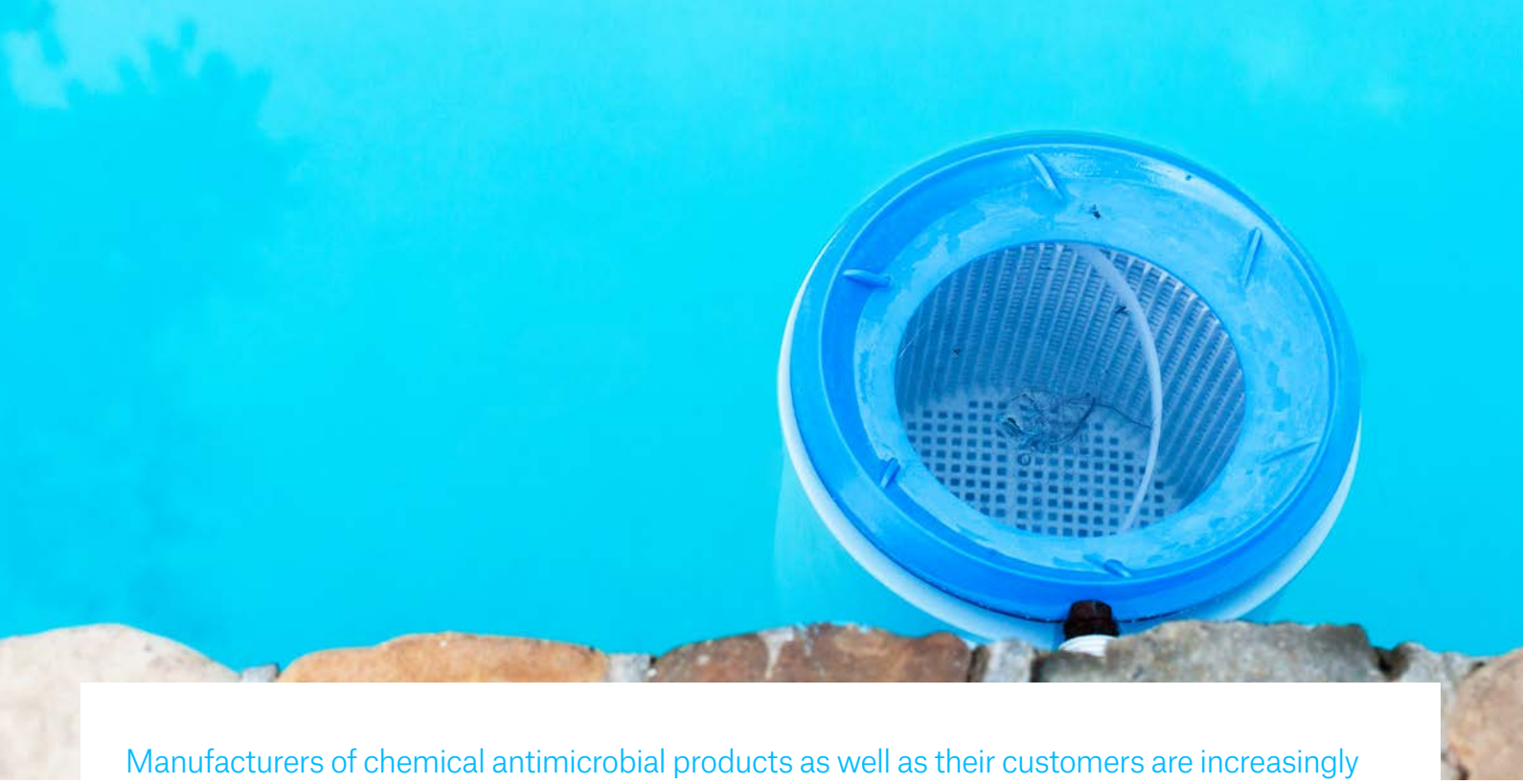
As the world becomes acutely aware of the importance of effective cleaning and disinfection, new and novel products that address the disinfection or sanitization of surfaces, water, and air are increasingly being developed and sold. Many non-chemical products, such as those that use UV light or ozone to kill microbial contamination, are becoming more prevalent in the US market. However, the regulatory landscape for approving such antimicrobial pesticide devices is not as straightforward as one may think.

In this paper, we discuss how antimicrobial pesticide devices are regulated in the United States (US) and provide recommendations on how companies can address their compliance obligations.





Manufacturers of chemical antimicrobial products as well as their customers are increasingly looking for alternative technologies to replace or supplement traditional antimicrobials. Institutions are developing more comprehensive processes to sanitize and disinfect the harder to reach surfaces in hospitals, offices and other public places. In addition, consumer demand is growing for different, often non-chemical options, to keep homes germ free.

Non-chemical products, such as UV light generators, air ozonation units, and water filters are increasingly being incorporated into sanitization and disinfection strategies as adjunct to primary disinfection methods. Referred to as "pesticide devices" by the US Environmental Protection Agency (EPA), these products do not go through the same rigorous registration standards as a "pesticide product".

While bringing antimicrobial pesticidal devices to market is significantly less onerous than for traditional chemical antimicrobial products, pesticide devices must still comply with various federal requirements and state registration standards. In addition, US EPA expects companies to have available all scientific data to support claims.

Going down the antimicrobial pesticide device route is also an attractive option for companies seeking to get antimicrobial products to market quickly at a potentially lower cost. However, before developing these novel products, it is important to ensure that the EPA deems the product a device versus an antimicrobial pesticide.

For all pesticide devices, it is also important to ensure that any efficacy claims are substantiated, both to provide consumer confidence, as well as meet EPA requirements.

So, what is a pesticide device, how are they regulated and how should efficacy claims be substantiated?

What is a pesticide device?

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulates antimicrobial pesticidal substances as well as pesticidal devices. The term "device" is defined in FIFRA 2(h) and subsequent EPA policy document [41 Fed. Reg. 51,065 (Nov. 19, 1976)] as:

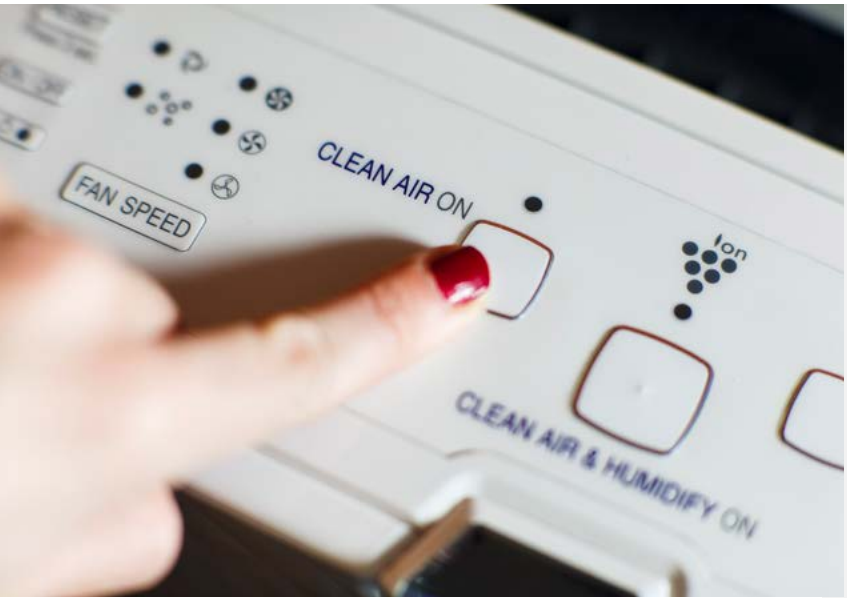
- Any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest
- An article that uses physical or mechanical means against a pest is a device

The 1976 policy declared many products to be devices including ultraviolet light systems, ozone generators, water and air filters (except those containing pesticides), and ultrasonic devices that claim to control fungi, bacteria, or viruses. The policy specifically called out that an article that incorporates a substance or mixture intended to control any pest is a pesticide. However, this specific carve-out has been the subject of confusion within the industry.

2007 policy

In 2007, a key policy was developed and published [72 Fed. Reg. 54,039 (Sept. 21, 2007)], clarifying the key distinction between pesticides and devices. The distinction centers on whether the pesticidal activity is due to a physical or mechanical action, or due to a substance or mixture of substances. The policy related to ion generators, which the EPA declared as no longer devices, but pesticides. Essentially, ion generators that use electrodes (of copper or silver) emit ions when a current is passed through. These electrodes give the ion generator its efficacy, and as such act as pesticides because the released ions prevent or destroy pests in a non-mechanical manner.

While related to ion generators, the policy established a precedent for how the EPA reviews and decides whether a product is a pesticide or a pesticidal device.



The EPA's 2007 policy on ion generators distinguished pesticides from devices. Because ion generators release a substance that accomplishes a pesticidal function, versus mechanically mitigating the pest, they are considered pesticides under FIFRA and must be registered appropriately prior to distribution.

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What are the regulatory requirements for pesticidal devices?

Federal requirements

While pesticide devices do not require registration, they are subject to certain requirements under FIFRA as specified in 40 CFR 152.500.

Production requirements

Pesticidal devices must be produced in an EPA registered pesticide device producing establishment and report annually on production.

Labeling requirements

Devices are subject to the labeling requirements in 40 CFR Part 156 and would be considered misbranded and subject to enforcement action if:

- The labeling bears any statements, designs, or graphic representations that are false or misleading (see 40 CFR 156.10(a)(5))
- It is an imitation of, or is offered for sale under the name of another device
- The label fails to bear the establishment number of the establishment where it was produced
- Any required information is not prominently displayed on the label
- It lacks adequate directions for use
- It lacks an adequate warning or caution statement

Child-resistant packaging

Devices are subject to child-resistant packaging (CRP) requirements when they meet certain toxicity and use criteria. See 40 CFR 157.20 – 157.36

Import and export of devices

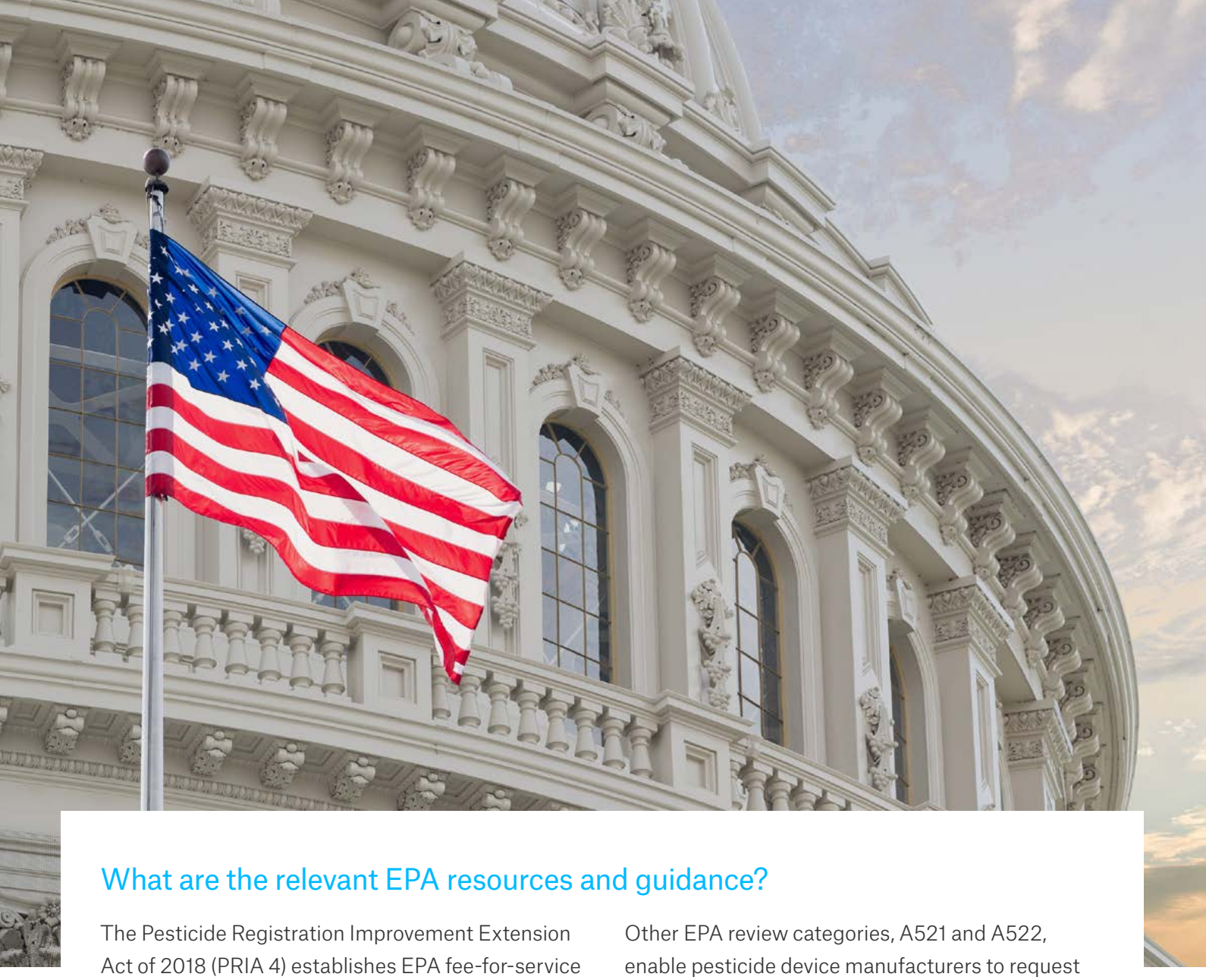
- Importers of devices into the United States must notify CBP of the arrival of imported pesticides and devices through the Notice of Arrival form (EPA Form 3540-1) prior to importation. The importer must submit the form to the EPA regional office applicable to the intended port of entry.
- With respect to the export of pesticidal devices, FIFRA Section 17 permits a pesticidal device to be lawfully exported “when prepared or packed according to the specifications or directions of the foreign purchaser”. This is only if certain FIFRA labeling requirements, establishment registration requirements, and requirements on the registrant to maintain books and records are met. Among other requirements, FIFRA requires that the label warning and caution statements be provided in both English and in the appropriate language of the country to which the pesticidal device is exported. The label must also bear “Not Registered for Use in the United States of America”. Since devices do not require registration, explanatory language can be included, such as “Because pesticide devices are not required to be registered in the United States.”

State requirements

Although devices are exempt from federal registration, several states require registration including:

- Colorado
- District of Columbia
- Hawaii (determines need for registration based on labeling and claims)
- Indiana
- New Mexico (only if contains bait or is battery operated)
- Oklahoma
- West Virginia
- Wyoming
- Puerto Rico

If the pesticidal device is packaged with an EPA registered product, then additional states will require registration. Applications for pesticidal devices can include product performance data to demonstrate efficacy, circuit diagrams, and in some states, submission of sample devices. After registration is obtained, licensing must be maintained and renewed annually or biannually depending on the state. For products that have been discontinued by a company, most states require that the product registration continue to be maintained (renewed) for a sufficient amount of time, typically two years, to clear the channels of trade.



What are the relevant EPA resources and guidance?

The Pesticide Registration Improvement Extension Act of 2018 (PRIA 4) establishes EPA fee-for-service review categories associated with pesticidal devices.

One review category, M009 Non-FIFRA Regulated Determination, enables companies to obtain a formal determination from the EPA as to whether a product meets the definition of a pesticide device or a pesticide product. The EPA timeline and cost associated with this review is four months and 21 days with a $2,482 fee. Since the regulatory requirements are very different between devices and pesticides, understanding the EPA's position can be very important.

Other EPA review categories, A521 and A522, enable pesticide device manufacturers to request the EPA to review pesticidal device efficacy protocols and data. The review process determines whether the protocol is appropriate to substantiate the public health efficacy claims a company would like to make on the device. The EPA timelines and cost associated with these review types can range from four to twelve months, costing $4,963 and $12,764 respectively.

Despite the fact these review categories have been established under PRIA 4, very few, if any, submissions have been made to EPA. This could be in part due to companies being nervous about receiving EPA guidance that is unfavourable. Since enforcement is relatively low for pesticidal devices, companies may decide to take the business risk to sell their product without EPA confirmation.

How may a company substantiate efficacy claims?

According to the EPA regulations, pesticidal devices may not make any false or misleading claims but it is not entirely clear what that means. As a result, device manufacturers will turn each other in to the Federal Trade Commission (FTC) for making "false and misleading" statements, making them subject to FTC enforcement.

EPA established the aforementioned categories, A521 and A522, to review testing protocols for substantiating public health efficacy claims. However, the EPA has not clearly established that pesticidal devices must meet the same performance standards as chemical antimicrobials in order to make claims such as "disinfection" and "sanitization". Users of pesticidal devices should therefore understand that a pesticidal device that claims to "disinfect" or "sanitize" may not kill organisms at the same rigorous log reduction and contact time as traditional liquid and wipe antimicrobial products.

Despite the ambiguous regulatory requirements, it is important that companies have data to substantiate product claims to win customer confidence. The goal should be to generate appropriate data that not only supports marketing claims, but also doubles as acceptable data by the EPA and the FTC. This means that study methods must be tailored to meet the needs of the device being tested and any desired claims. Solid study design and protocol development before testing begins is therefore crucial. No one wants to find out at the end of a study (and after the bill has been paid) that the data collected does not speak to the needs of the marketing and regulatory departments.

Once the data is generated, it will often require some statistical analysis which must be translated into plain language. The layman's translation must not only be factually accurate, but also understandable to the consumer and other company stakeholders.

Key takeaways

Antimicrobial pesticide devices have long been a subset of the traditional pesticide device market, which includes bug zappers and anti-gopher sound generators. Like their traditional cousins, the sale and distribution of antimicrobial pesticide devices in the US is regulated by EPA. As we have discussed, these regulations are not always well understood, defined, or enforced. Additionally, the state registration requirements for these products is ever-changing and evolving.

A full understanding of the regulatory environment is important for determining what steps your company can and should take to allow for the sale and distribution of a pesticide device in the US. Substantiating claims, as well as getting EPA to verify those claims, are often forgotten tools – they can assist in setting a product apart in the market place and help avoid accusations of misbranding.

FIFRA device determination is another infrequently used method of establishing the legal requirements associated with the sale of a product and should be used when the producer is unclear of how EPA may view a device. This may be especially useful for novel devices.

Lastly, ensuring that your device is appropriately manufactured, labeled, and has the necessary state registrations is crucial. Though the requirements for sale of a pesticide device may seem minor, being knowledgeable of what is required will help ensure the uninterrupted sale of your product in the US.

How TSG can help

TSG has extensive experience helping companies navigate the US regulatory requirements for pesticide devices. Our services include:

- Helping identify if a product is a pesticide or a pesticide device, and detailing the applicable data requirements
- Developing appropriate test methodology and solid study designs
- Interacting with contract labs on behalf of clients for protocol development and to monitor the testing processes
- Analyzing, interpreting and communicating the results – in layman's terms – for marketing and business development needs
- Preparing and submitting state registration packages
- Preparing and submitting establishment registration and annual production reports

For guidance on bringing your pesticidal device to market in the US, contact TSG at:

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Notes

About TSG Consulting

TSG Consulting provides companies with high-quality regulatory and scientific consulting services.

We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

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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About Science Group plc

Science Group plc (AIM:SAG) is an international, science-led services and product development organization. Its specialist companies, TSG Consulting, Sagentia, Oakland Innovation, OTM Consulting, Leatherhead Food Research and Frontier Smart Technologies, support the product innovation lifecycle, enabling clients to deliver on their investments in R&D.

Science Group's services fall into four broad categories: Applied Science, Product Development, Technology Advisory and Regulatory. These services are combined with vertical market expertise in the Medical, Consumer, Food & Beverage, Industrial, Chemical and Energy sectors. With offices throughout Europe, North America and China/Hong Kong and with over 30 languages written and spoken, Science Group supports a global client base.

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