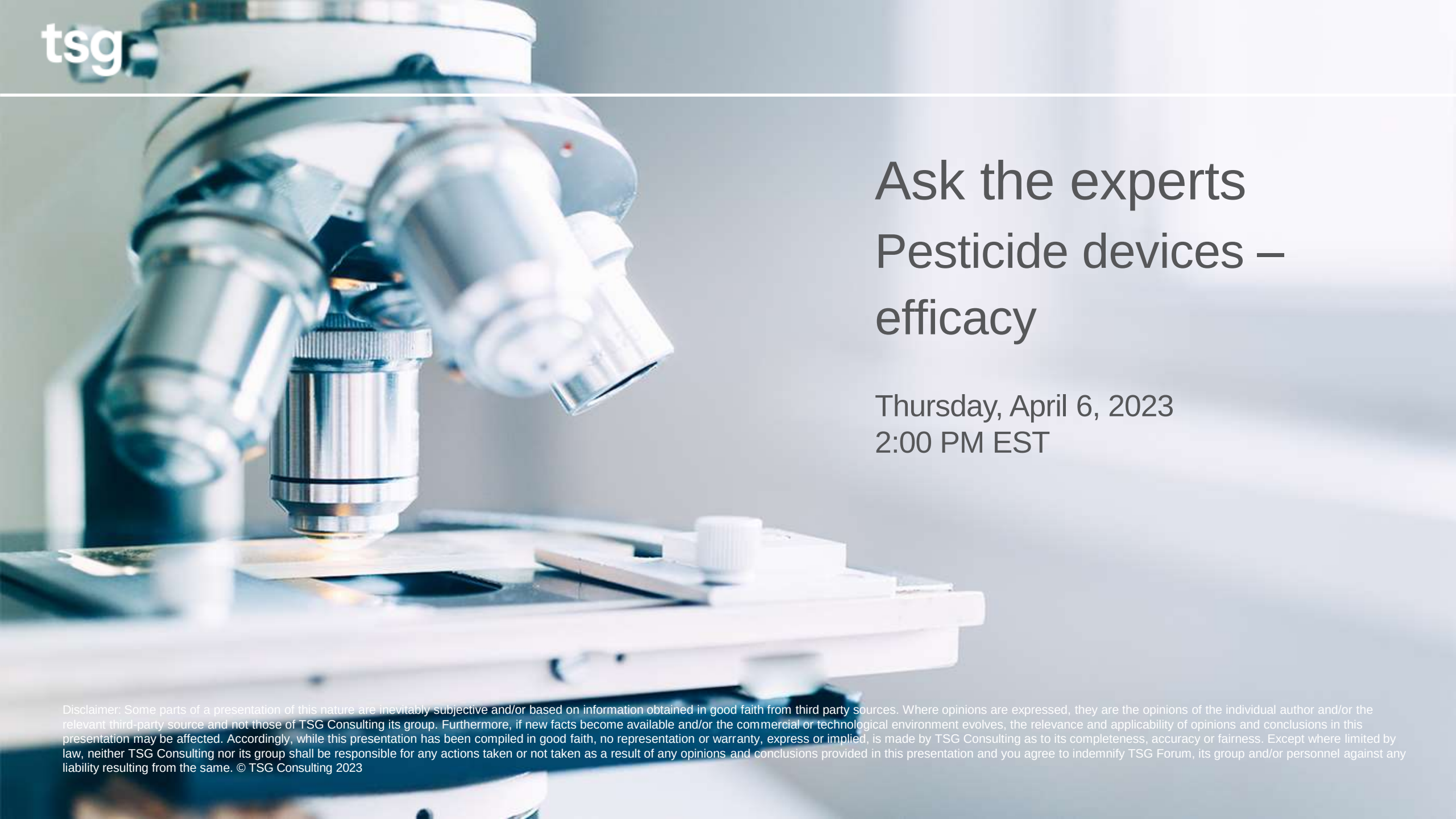

Ask the experts
Pesticide devices – efficacy

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2:00 PM EST

Meet the experts

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Senior Regulatory Consultant

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About TSG Consulting

Regulatory and science-based services for the chemical, plant protection, biocides, medical device, and related industries

North America & Europe
Consultants located across North America & Europe

Regulatory experience
Many consultants formerly held positions at the UK CRD, ECHA, USDA, EPA, CPSC or were regulatory lawyers

Scientists
Specialists in toxicology, ecotoxicology, e-fate, FOCUS modelling, efficacy, chemistry, microbiology, biology, entomology, biochemistry, zoology, environmental studies

30+
Year history with deep regulatory relationships

100+
Consultants and scientists across North America & Europe

33
Plant protection experts

18
Biocide/ antimicrobial experts

11
Chemical experts

10
Ex regulators (UK CRD, FDA, USDA, EPA)

14
Industry trade associations we actively participate in

Understanding the efficacy requirements associated with pesticide devices

Federal regulations for devices

Devices regulated under Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

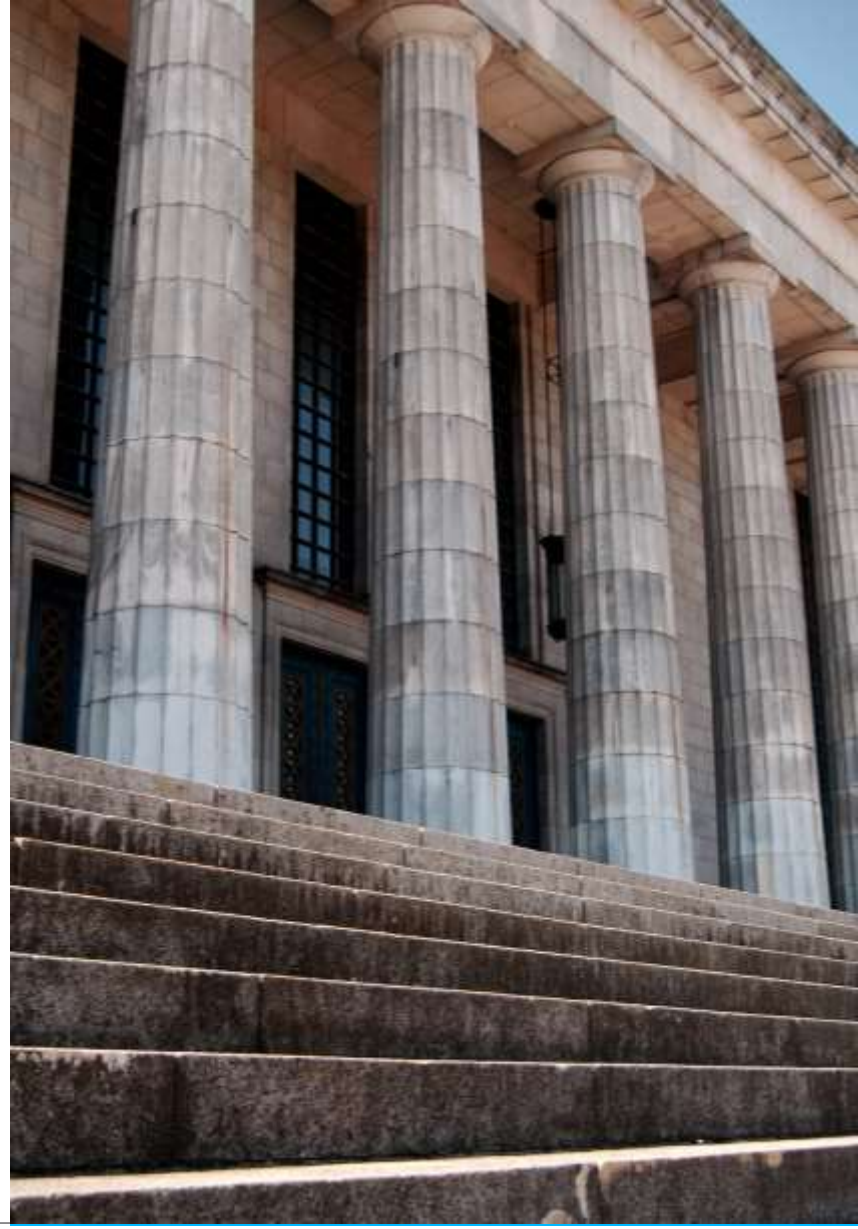
Administered by the US Environmental Protection Agency (EPA)

Regulates: composition, testing, registration, labeling, promotion, distribution, sale, and use of “pesticides” and “pesticidal devices”

- Pesticide devices are not subject to registration requirements but there are several regulatory requirements before distribution or sale
- Federal guidance for pesticide devices are minimal and EPA has increased enforcement. It is like the, “wild west” as compared to traditional pesticides
- EPA has not released any test methods for devices. Industry must rely on EPA’s Series 810 guidelines for devices that make public health claims

Recent federal legislation for devices

- In December 2022, US Congress enacted the fifth iteration of the Pesticide Registration Improvement Act (PRIA V)
- EPA to set aside funds for the development of public health performance standards for pesticide devices
- $500,000 will be set aside to develop efficacy test methods for antimicrobial pesticide devices making public health claims over the next 5 years
- Creation of workgroup called DFJ (Devices and FIFRA Jurisdiction) in Antimicrobial Division, dedicated to development of regulations and testing guidelines for pesticide devices



General requirements for devices

- No testing requirements or guidelines at the federal level (not yet)
- Devices must not include “false or misleading claims” on their label or labeling
- Specific labeling and recording keeping requirements
- Device manufactures, sellers, and/ or distributors are responsible for maintaining records and data to support their claims
- Product claims are substantiated with data – and the data you need is dictated by the claim to be made
- An example of a false/misleading claim about the product’s effectiveness is one for which you have no supporting scientific data

Avoid false or misleading claims

EPA

- Section 2(q)(1)(A) of FIFRA
- Misbranded if “its labelling bears any statement, design or graphic representation which is false or misleading in any particular manner.”
- EPA AD is working with OECA (Office of Enforcement Compliance Assurance) and OGC (Office of General Council) to develop guidance on false and misleading claims to share with EPA Regions

Federal Trade Commission

- The FTC Act prohibits unfair or deceptive advertising in any medium. Advertising must tell the truth and not mislead consumers
- A claim can be misleading if relevant information is left out or if the claim or implies something that's not true
- All claims must be substantiated, especially when they concern health, safety, or performance

Substantiating claims

Producers and sellers must ensure the device performs as claimed on the label, making proper advertising and marketing claims

- Avoid being reported to the EPA or FTC by competitors
- Avoid Federal and State level enforcement
- Provide fact-based evidence science to support product claims
- Accurately incorporate claims into overall positioning of device
- Company must maintain data and information which is used substantiate the product claims

Examples of false or misleading claims

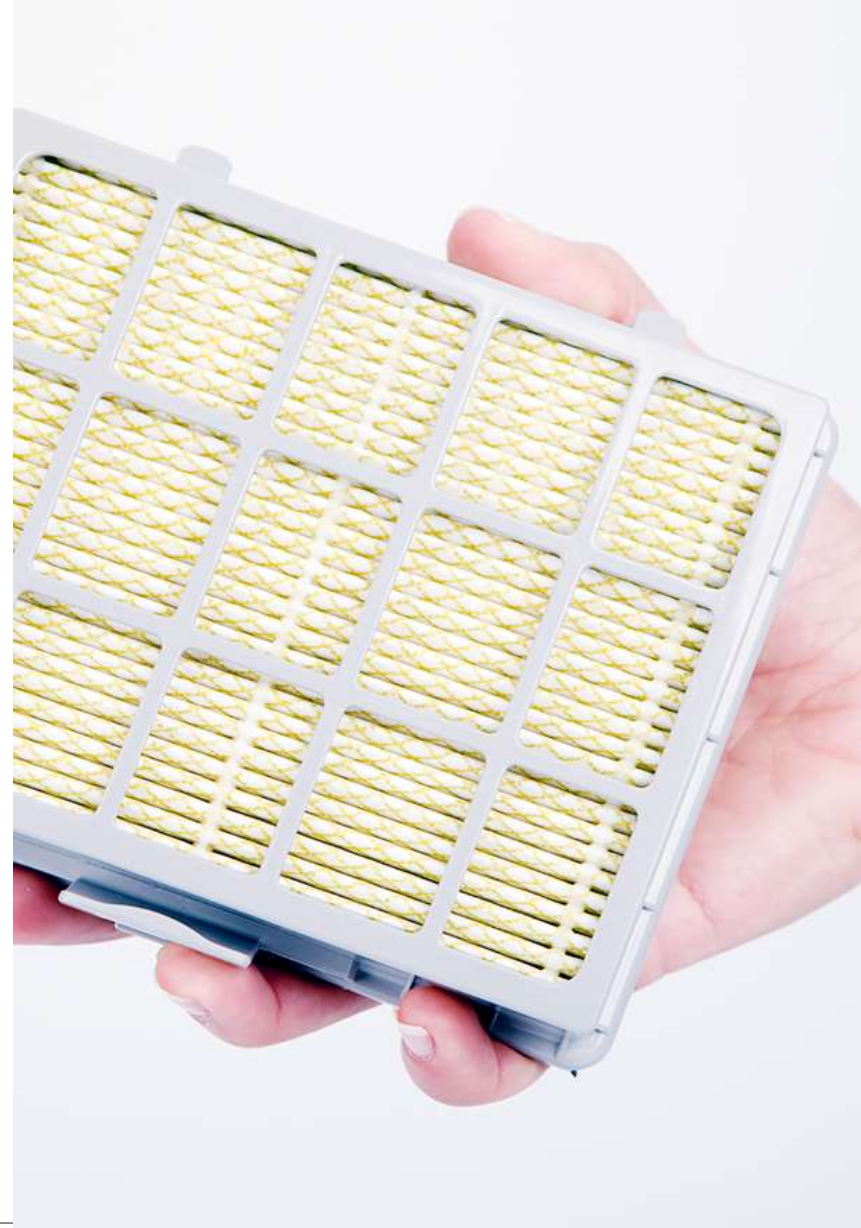
Marketing claim	Reality
Biodegradable	The product is made of components that are biodegradable, but the final product being sold itself is not. Note: The claim Biodegradable is unacceptable for any pesticide product
Protects or Prevents against COVID-19	COVID -19 is a disease not a pathogen. Product must be tested against SARS-CoV2 virus that causes COVID-19
Kills in 30 seconds	Only 1 or 2 of the organisms tested are killed in 30 seconds and the remaining organisms have a 10-minute dwell time
Safe and more effective than traditional pesticides	This is an unqualified claim (how is the product more effective?) and comparing to other products
Better than the leading brand	This is subjective (better how) and want to avoid comparative claims to other devices or products

Pesticide Device Determination

- What is a device determination?
- This is a voluntary process which EPA determines whether the product is a pesticide or a device
- Device determination at EPA fall under PRIA Fee Category M009 - Non-FIFRA Regulated Determination: Applicant initiated, per product
  - 6 month and 21-day EPA review time, $3,389 EPA registration service fee
  - Provide specific details about device and labeling

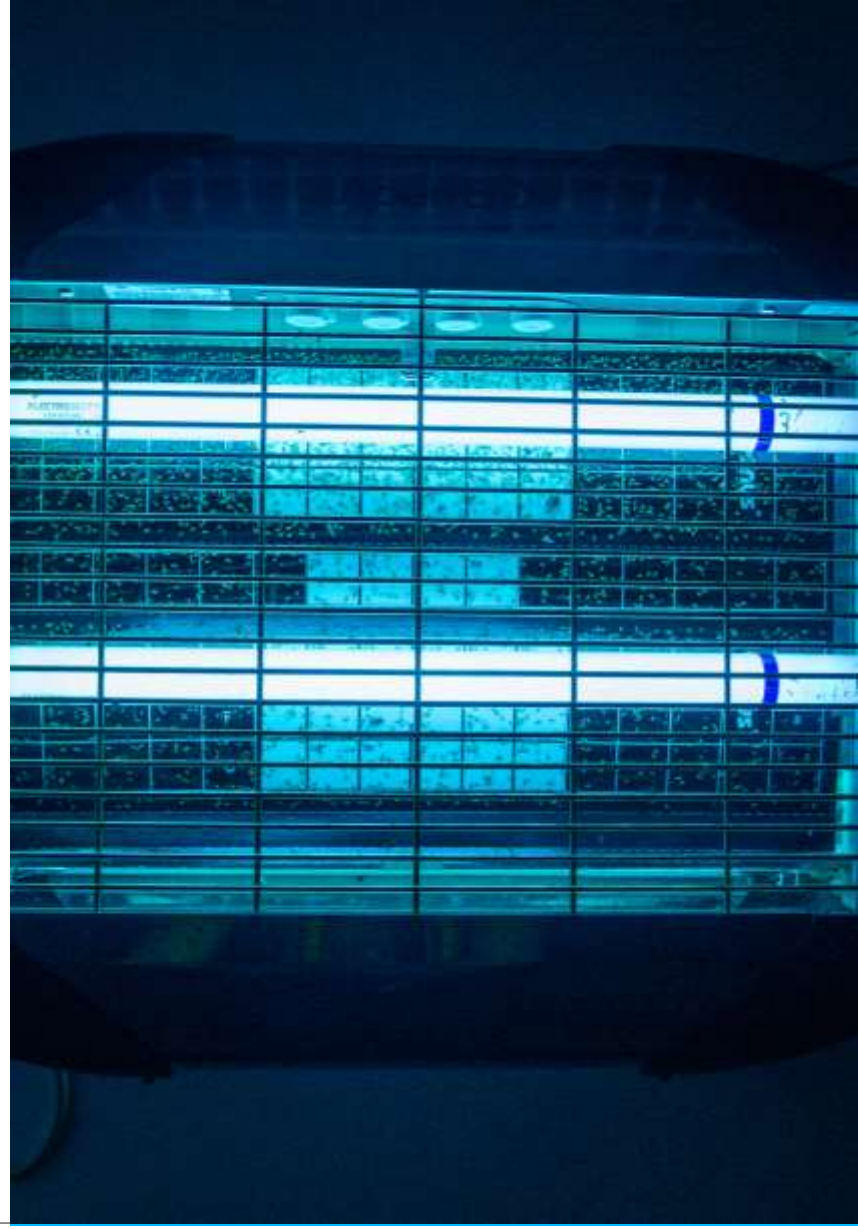
State efficacy guidelines

- States will review efficacy data
- Efficacy data must be run on worst-case label scenario
- With the absence of standard guidelines, states will default to the 25b working group efficacy guidance for non-antimicrobials
- For antimicrobials, we default to the 810 guidelines



Non-antimicrobial efficacy guidelines

- Non-antimicrobial efficacy
  - Data must be based on sound scientific principles but does not need to be GLP
  - Testimonials are not acceptable and journal articles are rarely accepted
  - In-house studies may be acceptable if conducted in a GLP-like manner with a qualified study director
  - Surrogacy scheme limited to non-public health pests
  - Mosquito data must be run on Anopheles, Aedes or Culex
  - Tick data must be run on Blacklegged, American, Brown or Lone Star
  - Spatial repellents – 75%
  - Public health pests – 80%
  - Non-public health pests – 60%
  - Soft claims may be allowed when performance criteria is not met



Antimicrobial efficacy

Example of regulated device

- Ultraviolet light units: claim to kill, inactivate, or suppress growth of microorganisms such as fungi, bacteria or viruses
- Water purifiers or water treatment units: claim to kill, inactivate, or suppress growth of fungi, algae, bacteria, viruses, or cysts

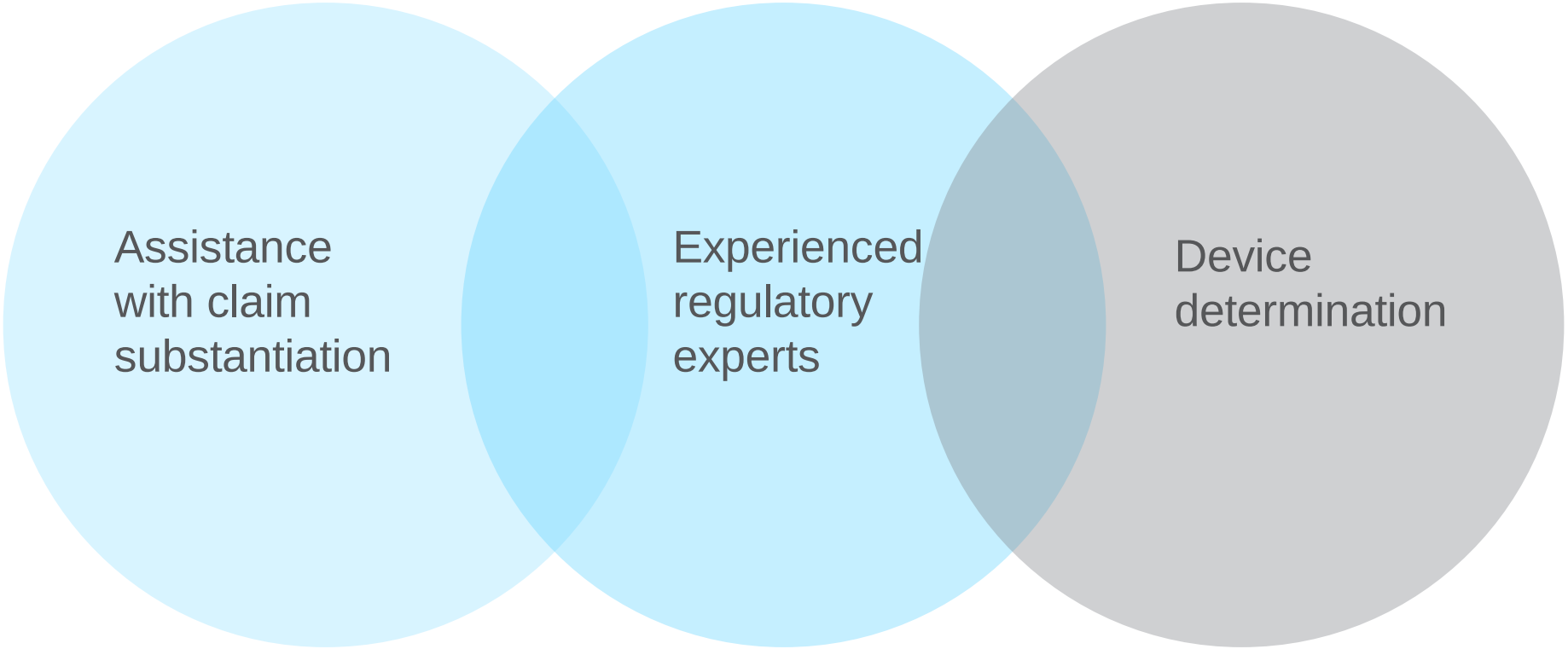
Antimicrobial efficacy

State regulators recommend efficacy for antimicrobial public health claims follow the 810 Guidelines for example:

"Kill Germs"	Kill -or- eliminate -or- destroy -or- remove 99.9% of bacteria
Staphylococcus aureus *Salmonella enterica* *Pseudomonas aeruginosa* Viruses and /or Fungi	*Staphylococcus aureus* *Klebsiella pneumoniae* *Or* *Klebsiella aerogenes*

- Number of devices – 2

How can TSG help?



Key takeaway

Lack of established efficacy guidelines specific to devices is a two-sided coin. It allows for flexibility but also drives uncertainty

Thank you

Q&A

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