



Overview of Antimicrobial Product Registration and Devices

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Office of Chemical
Safety and Pollution
Prevention (OCSPP)

Office of Pollution
Prevention and
Toxics (OPPT)

Office of Pesticide
Programs (OPP)



Federal Pesticide Laws

- **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)** - Requires all pesticides sold or distributed in the United States to be registered by EPA.
- **Federal Food, Drug and Cosmetic Act (FFDCA)** - Requires EPA to set pesticide tolerances for all pesticides used in or on food or in a manner that will result in a residue in or on food or animal feed.
- **Food Quality Protection Act, of 1996 (FQPA)**, which amended both FIFRA and FFDCA, EPA must find that a pesticide poses a "reasonable certainty of no harm" before it can be registered.
- The **Endangered Species Act (ESA)** requires federal agencies to ensure that any action they authorize, fund, or carry out, will not likely jeopardize the continued existence of any listed species, or destroy or adversely modify any critical habitat for those species.
- The **Pesticide Registration Improvement Act (PRIA)** requires companies to pay service fees according to the category of the registration action and requires EPA to meet decision review time periods, which result in a more predictable evaluation process for companies.



What's a pesticide?

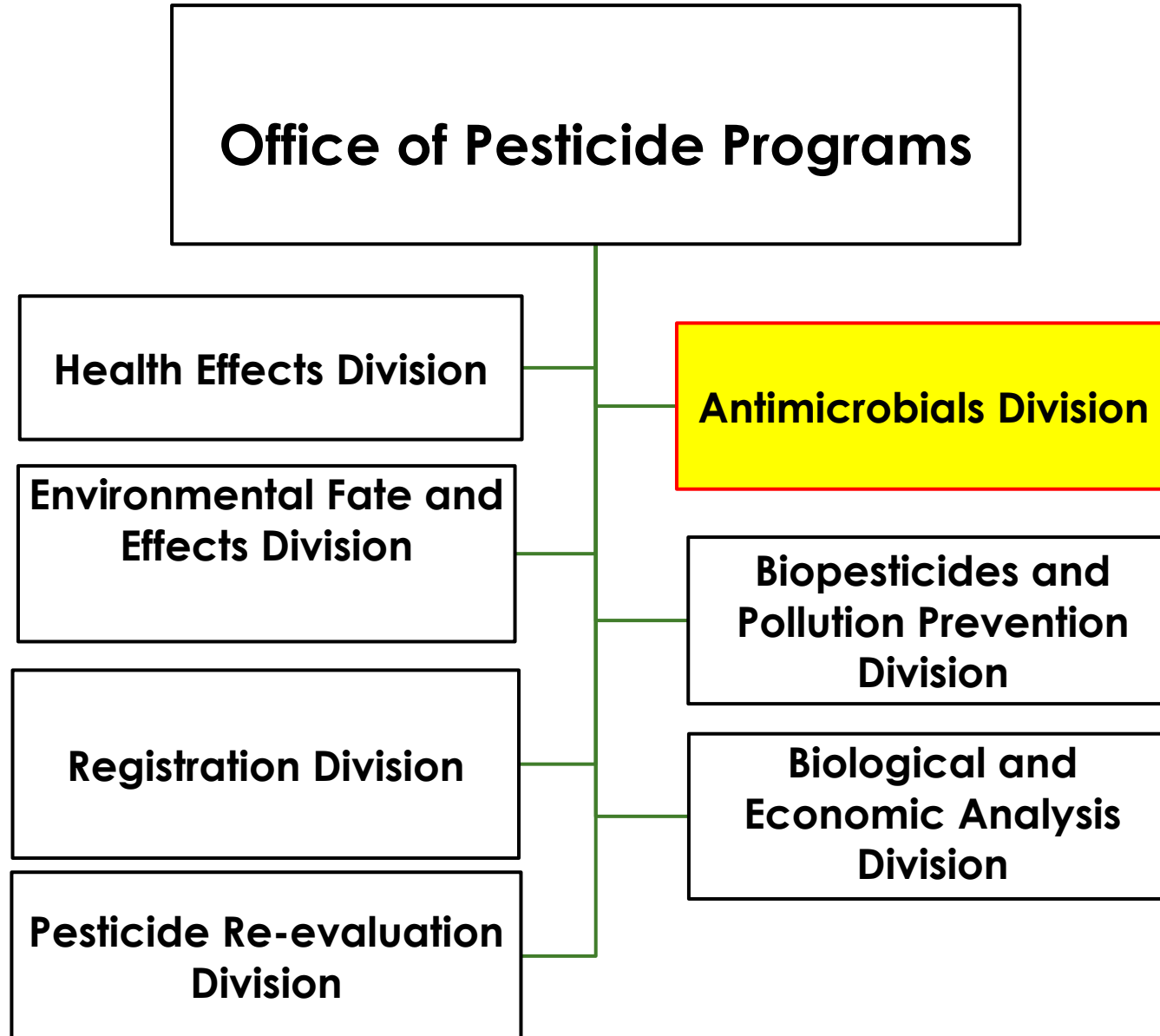
The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) defines

- a pesticide as **any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant.**
- a “**pest**” broadly to include “(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or **virus, bacteria, or other micro-organism** (except viruses, bacteria, or other micro-organisms on or in living man or other animals).”
- FIFRA requires all pesticides sold or distributed in the United States (including imported pesticides) to be registered by EPA.



Types of Pesticides

- Antimicrobial pesticides, substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms whether bacteria, viruses, or fungi on inanimate objects and surfaces.
- Biopesticides, types of pesticides derived from certain natural materials.
- Conventional pesticides, includes all ingredients other than biological pesticides and antimicrobial pesticides.
- Inert ingredients, substances contained in pesticides in addition to the active ingredient(s).





AD: Self-Contained Division – “Mini-OPP”

Branch	Responsibilities	Key Staff
Risk Assessment Branch I	<ul style="list-style-type: none">• Human Health Risk Assessment• Ecological Toxicology and Environmental Fate Risk Assessment	<ul style="list-style-type: none">• Exposure, Fate, Hazard, and Risk Assessors
Risk Assessment Branch II		
Efficacy Branch	<ul style="list-style-type: none">• Product Efficacy	<ul style="list-style-type: none">• Microbiologist/biologists
Regulatory Management Branch I	<ul style="list-style-type: none">• Registration/PRIA	<ul style="list-style-type: none">• Product Managers• Product Reviewers
Regulatory Management Branch II		
Regulatory Management and Science Branch	<ul style="list-style-type: none">• Registration/PRIA• Acute Toxicity• Product Chemistry	<ul style="list-style-type: none">• Product Managers• Product Reviewers• Toxicology and Product chemists
Re-evaluation Branch	<ul style="list-style-type: none">• Re-registration/Registration review	<ul style="list-style-type: none">• Chemical Review Managers



Types of Antimicrobial Products

Public health products

- Are intended to control microorganisms infectious to humans in any inanimate environment.

Non-public-health products

- Are used to control growth of microorganisms of economic and aesthetic significance and are not considered to be human health related





Antimicrobial Efficacy Claims

Antimicrobial Pesticides

- Destroy or suppress microorganisms in the inanimate environment
- Registrant must substantiate pesticidal claims with efficacy data

Public Health

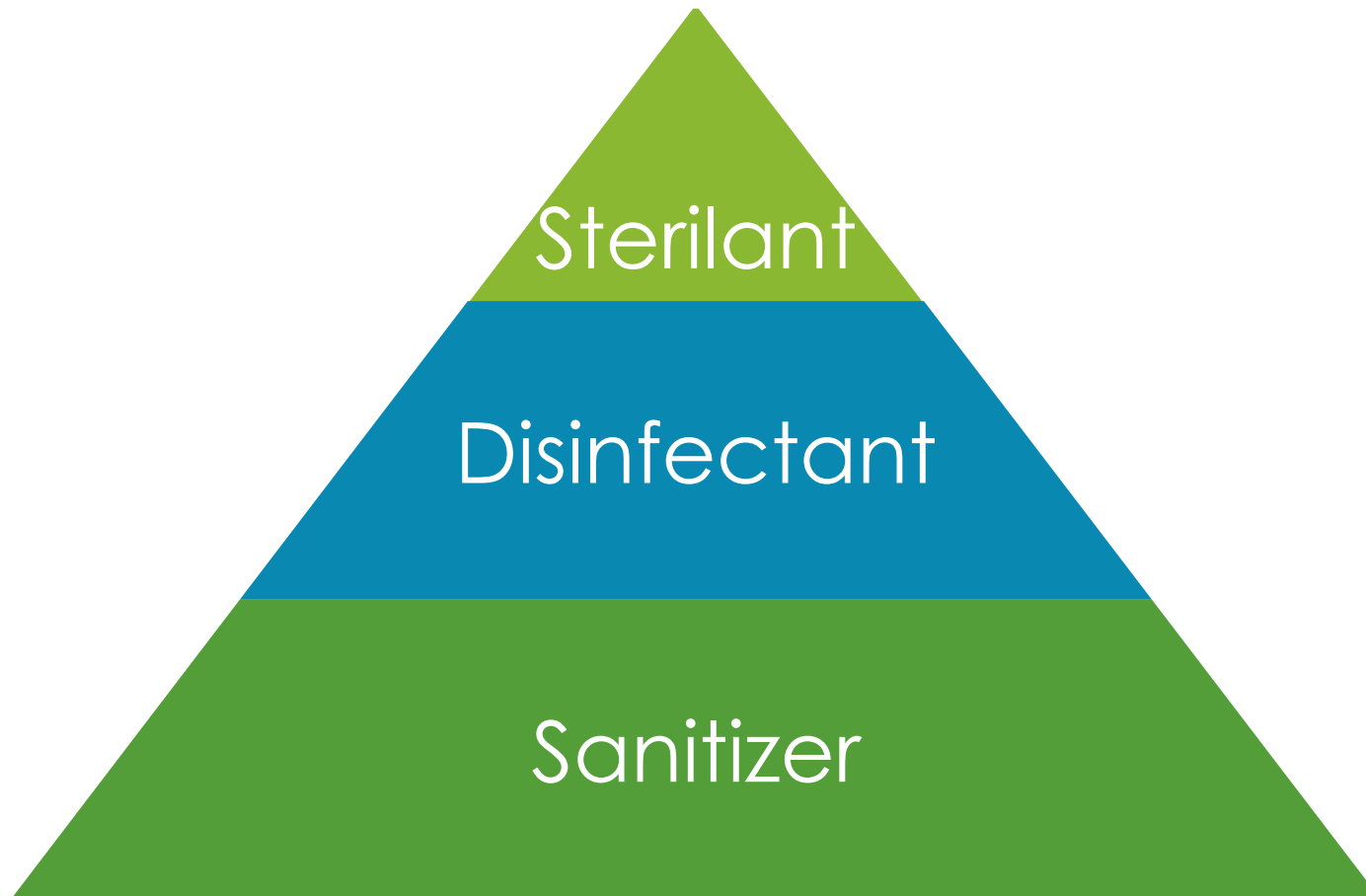
- Claim to control microorganisms affecting human health
- Require efficacy data to be reviewed by EPA

Non-Public Health

- No claim to control microorganisms affecting human health
- Do not require efficacy data to be reviewed for registration

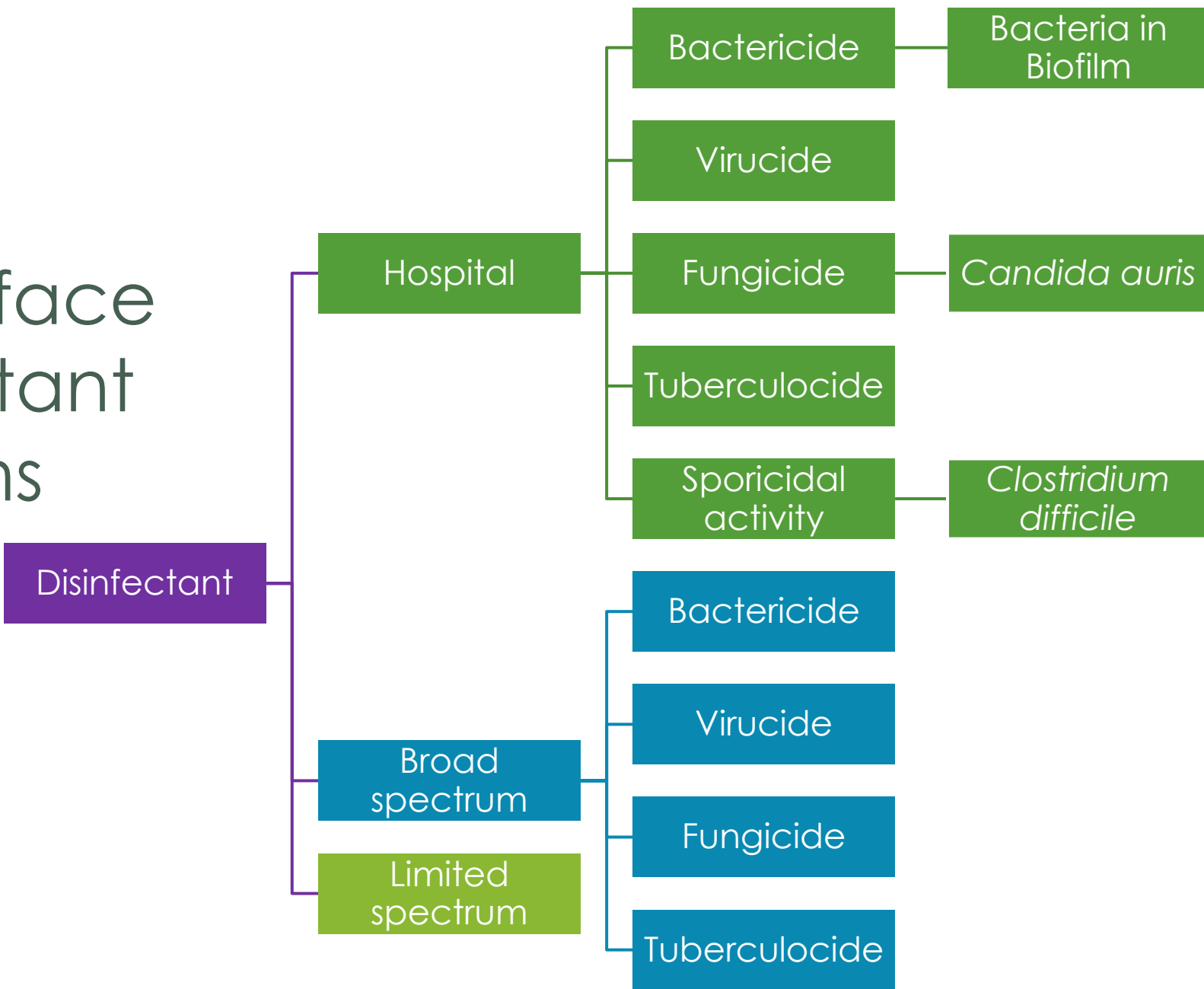


Levels of Efficacy





Hard Surface Disinfectant Claims





Antimicrobial Major Use Sites

- Home
- Hospital
- Water
- Preservatives



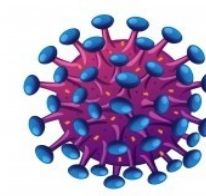
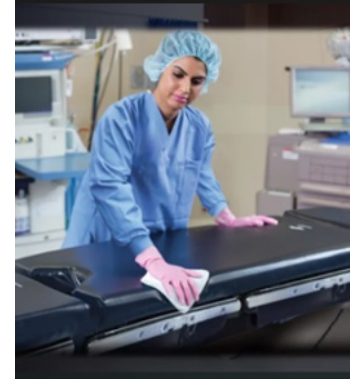
Residential Pesticide Products

- Some AD pesticides are available to the public
 - Nonpublic health and public health claims
 - Products are used in everyday households
 - These include sanitizers and disinfectants
- Difference between cleaner and pesticide:
 - Cleaners are considered non-pesticidal
 - Example -Removes grease and grime
 - A pesticide is a product that makes kill claims to specific organisms
 - Example: "Kills *Salmonella aeruginosa*"

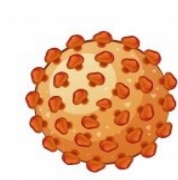


EPA Health Care Products

- **Used in hospitals** to disinfect hospital rooms and commonly touched surfaces
- Disinfection is important to **reduce patient contact** for pathogens.
- **Main registered active ingredients with hospital uses:** quats, hydrogen peroxide and bleach
- All undergo **rigorous label and scientific efficacy review** to make sure they're up to the task



HIV



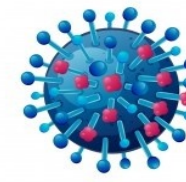
Hepatitis B



Ebola Virus



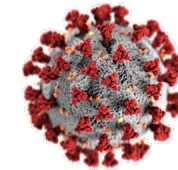
Adenovirus



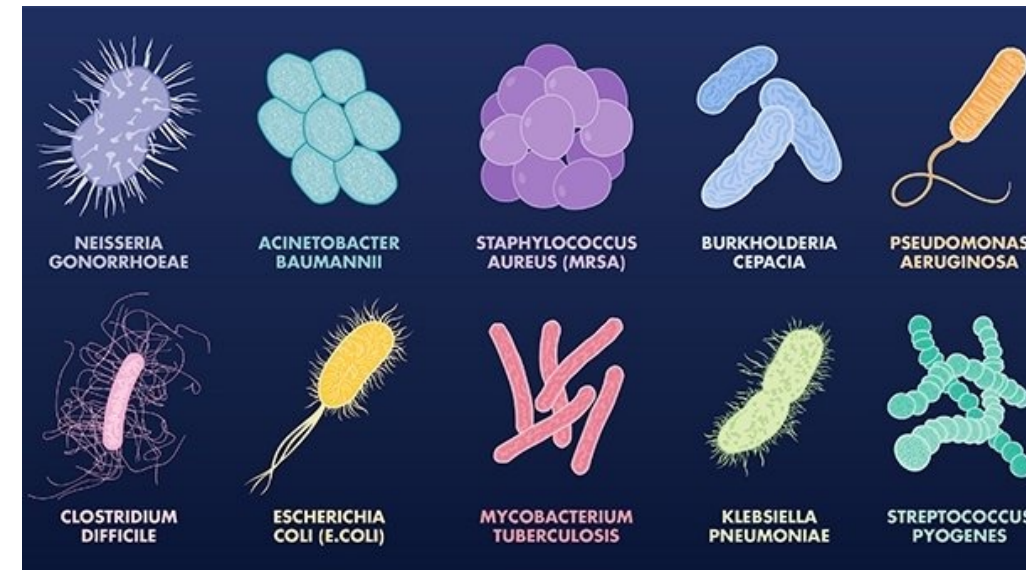
Influenza



Bacteriophage



SARS-CoV-2



Preservatives

- Almost everything you touch or interact with has pesticides incorporated in them
- Preserves product integrity and your safety
- Referred to as “materials preservatives”
- Materials Include:
 - Plastics
 - Fabrics
 - Metalworking fluid
 - Wood
 - Other pesticide products



Aquatic Areas/Pools

- Swimming Pools/Hot tubs
- Fountains
- Ornamental Ponds
- Water treatment (drinking and waste)





Food Contact

- When an antimicrobial pesticide is intended to be directly applied to food for the purposes of treating food.
- We also have products that are applied to dishes, counter tops, and other indirect food contact sites





EPA List N: Disinfectants for use against SARS-CoV-2

- On March 5, 2020 EPA posted [List N: Disinfectants for Use Against SARS-CoV-2](#)
 - Initial list contained ~90 products
- The most recent list N update has over 540 products
- Significant improvements to the list have been made including:
 - the ability to search and sort a dynamic list
 - additional information helpful to end users (e.g., active ingredient, formulation type, use sites)
- Most recently EPA deployed a new app-based tool

List N: Disinfectants for Use Against SARS-CoV-2

All products on this list meet [EPA's criteria](#) for use against SARS-CoV-2, the virus that causes COVID-19.

Finding a Product

To find a product, enter **the first two sets** of its **EPA registration number** into the search bar below. You can find this number by looking for the EPA Reg. No. on the product label.

For example, if EPA Reg. No. 12345-12 is on List N, you can buy EPA Reg. No. 12345-12-2567 and know you're getting an equivalent product.

[Search by EPA registration number](#)

NEW View List N's information in our new tool

EPA Registration Number
Active Ingredient
Use Site
Contact Time
Browse All
Keyword Search



Pesticides vs Devices – Federal Insecticide

Fungicide and Rodenticide Act (FIFRA) Authority

EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) has regulatory authority over both pesticides and devices.

- FIFRA defines a pesticide as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest...”
- FIFRA defines 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... but not including equipment used for the application of pesticides when sold separately therefrom.”





1976 Federal Register Notice Clarifications for Devices

- A device is an instrument or contrivance that works by physical means (such as electricity, light or mechanics.)
- Devices cannot contain a substance or mixture of substances intended to prevent, destroy, repel or mitigate any pest.
- EPA considers generators of pesticidal solutions when sold without substances to be devices, e.g., hypochlorous acid generator sold without salt.

Examples: fly traps, fly ribbons, black light traps, sound generators, air and water filters, carbide cannons, UV lights, ozone generators





Device vs. Pesticide Regulation

	Device	Pesticide
Comprehensive premarket review and registration	No	Yes
Submission/EPA review of public health efficacy data and claims	No	Yes
Labeling requirements (For devices – FIFRA Section 2q(1) and 40 CFR Part 156)	Yes; (limited Agency feedback; No false or misleading claims)	Yes
Production requirements under FIFRA Section 7 and 40 CFR Part 167	Yes	Yes



EPA Coordination on UV Lights

- Internal coordination: the Office of Pesticide Programs (OPP) interacts with Office of Research and Development, Office of Air and Radiation and the Office of Water.
 - Enforcement assistance to the Office of Enforcement and Compliance Assurance and regional offices.
- Federal Coordination: OPP interacts most frequently with the Food and Drug Administration (devices and radiation safety), the Consumer Product Safety Commission and many other agencies related to the pandemic.
- State and tribal co-regulators.



Summary of Challenges:

- EPA faces many challenges in regulating devices because the current regulatory framework does not allow for pre-market review of product safety or efficacy claims and does not address the complexity of devices available on the market today.
- Resource constraints limit the ability to undertake regulatory changes at this time.
- Device products with claims to control SARS-CoV-2 have continued to expand during the pandemic.



Summary of Challenges:

- Public health consequences for insufficiently regulated devices.
 - Users may not use prudent disinfection processes if they believe they are protected by these technologies.
 - Users may believe they do not have to follow public health guidance, such as handwashing, wearing masks, social distancing, etc.

- Some devices may cause harm:
 - Some UV lights can cause burns of skin/eyes, skin cancer.
 - Some UV light devices generate ozone which can exacerbate asthma and chronic obstructive pulmonary disease.



Questions?



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