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OFFICE OF ENFORCEMENT
AND COMPLIANCE ASSURANCE

COMPLIANCE ADVISORY
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EPA Regulations About UV Lights that Claim to Kill or Be Effective Against Viruses and Bacteria

The primary purpose of this Compliance Advisory is to provide an explanation to the ultraviolet (UV) light industry that UV lights are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as pesticide devices when sold or distributed with claims to kill or be otherwise effective against viruses and/or bacteria, unless an exception applies, and must comply with certain statutory and regulatory requirements.

Are UV lights regulated by EPA?

UV lights that are sold or distributed with claims that the product can be used for preventing, destroying, repelling or mitigating any pest (plant, animal, virus, bacteria or other micro-organism) are federally regulated by EPA under FIFRA as a device, in particular FIFRA Sections 2(q) and Section 7. Generally, without such claims, a UV light would not be subject to FIFRA.

What is a pesticide device?

Under FIFRA, a pesticide device is an instrument that is used to destroy, repel, trap, or mitigate any pests. A device must work solely by physical means (such as electricity, light or mechanics). If the device incorporates a substance or mixture of substances to perform its intended pesticidal purpose, then it is considered a pesticide product, not a device.

How do I comply with FIFRA if I am selling or distributing a UV light with pesticidal claims?

- Devices do not need to be registered by EPA and, therefore, are not subject to a pre-market review by EPA (although some states require devices to be registered). However, federal regulations require devices to be produced in an EPA-registered pesticide producing establishment and there are production reporting requirements; see 40 C.F.R Part 167.

- Devices must be labeled per federal regulations at 40 C.F.R Part 156. Generally, device labels must include warning and caution statements, directions for use and the EPA establishment number, amongst other label requirements. A description of device label

- All claims in connection with the sale or distribution of a device must be true and not misleading. FIFRA Section 12(a)(1)(F) specifically prohibits false or misleading labeling (known as misbranding); this includes claims made in marketing materials and on websites. Examples of misbranding are provided at 40 C.F.R 156.10(a)(5) and include, but are not limited to, false or misleading statements concerning product effectiveness (known as efficacy), claims about product safety, false or misleading comparisons with other pesticides or devices, or any statement directly or indirectly implying that the device is recommended or endorsed by any agency of the Federal Government. Companies are advised to maintain records, with information and data, to substantiate that claims made in regard to devices are not false or misleading.

In addition to FIFRA requirements, importers of all FIFRA-regulated devices must comply with the U.S. Customs and Border Protection (CBP) regulations set forth at 19 C.F.R. §§ 12.110 - 12.117. Regulated entities that are importing UV pesticide devices are advised that the products being imported must be in compliance with FIFRA prior to entry into the United States. The EPA regularly coordinates with CBP to identify and reject violative UV pesticide devices at the port of entry.

Can a UV light be a pesticide requiring EPA registration?

Yes. If the UV light product incorporates a substance or mixture of substances to perform its intended pesticidal purpose, then it is considered a *pesticide product*, not a device, and must be registered with EPA in accordance with FIFRA Section 3 before it can be lawfully sold or distributed in the United States.

Are UV lights safe and effective?

Unlike chemical pesticides, EPA does not routinely review the safety or efficacy of UV light devices and, therefore, EPA has not conducted a human health risk assessment to determine the safety of these products. For the same reason, EPA cannot confirm whether, or under what circumstances, UV light devices might be effective against any pest, including viruses and bacteria. The effectiveness of any UV light device will depend on a variety of factors including, but not limited to, the device's duration of use, distance of the light from the surface intended to be treated, the UV wavelength, the specific pest being targeted, the strength or wattage of the UV light bulb, the age of the UV light bulb, shadow areas or other factors.

Consumers are advised to use all pesticidal devices ONLY in accordance with the Directions for Use, which are required to appear on the product label. EPA recommends that consumers contact the manufacturer or seller of the pesticidal device directly if they have any questions about how to use the product, the product's safety, or the product's efficacy.

What are the compliance concerns related to UV lights?

There may be members of the UV light industry who are unfamiliar with FIFRA and may not be aware of statutory and regulatory requirements. For example, they may be unaware that it is a violation of FIFRA to sell or distribute pesticidal UV light devices that are misbranded or that have not been produced in an EPA-registered establishment. EPA has been receiving complaints that UV light devices may be in violation of FIFRA. These complaints are being reviewed and EPA intends to pursue enforcement, as appropriate. See EPA's May 2020 compliance advisory on products making claims to kill the coronavirus that causes COVID 19 at
and any subsequent updates.

Regulated entities of any size who voluntarily discover, promptly disclose, expeditiously correct, and take steps to prevent recurrence of potential violations may be eligible for a reduction or elimination of any civil penalties that otherwise might apply. To learn more about the EPA's violation disclosure policies, including conditions for eligibility, please review EPA's Audit

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policing; please check with the appropriate state agency for more information.

Are you unsure if your product is a device under FIFRA?

EPA has developed a guide concerning pesticide devices that explains what a pesticide device and how it differs from a pesticide product which requires registration. This guide may be

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DISCLAIMER

Nothing in this Compliance Advisory is meant to replace or revise any EPA regulatory provisions of any other part of the Code of Federal Regulations, the Federal Register, or FIFRA.