



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF ENFORCEMENT
AND COMPLIANCE ASSURANCE

COMPLIANCE ADVISORY
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What You Need to Know About Producing, Distributing or Selling Pesticide Devices

The purpose of this Compliance Advisory is to provide critical information to the regulated community about producing, distributing, or selling pesticide devices.

The United States Environmental Protection Agency (EPA) regulates pesticide devices (herein “devices”) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and its implementing regulations. EPA does not register devices or require a pre-market review of devices and device labels. However, EPA may review device labels and labeling during compliance monitoring of domestic, imported or exported device products, or as part of voluntary, fee-based, regulatory determination submission. Devices are subject to statutory and regulatory requirements, and the failure to comply with applicable requirements may constitute an unlawful act. Failure to comply with FIFRA may result in a United States Customs and Border Protection (CBP) hold or denial at a port of entry, the issuance of a Stop Sale, Use, or Removal Order (SSURO), seizure, and/or the assessment of civil and/or criminal penalties.

Why Is EPA Issuing this Compliance Advisory?

There has been a significant increase in the number of devices being distributed or sold in the United States (U.S.). EPA has found substantial non-compliance with FIFRA in the device and pesticide marketplace. Examples of non-compliance include unregistered pesticides claiming to be devices, devices bearing false and misleading statements, and devices being sold and distributed that were not produced in an EPA registered establishment. EPA has also been receiving a high volume of inquiries from the regulated community and our co-regulators seeking information on how devices are regulated. The regulatory requirements for devices differ from those that apply to registered pesticide products. This compliance advisory is intended to

promote FIFRA compliance for devices by highlighting the pesticide regulations applicable to devices.

Is My Product a Device or a Pesticide?

A device is an instrument or contrivance that is intended to destroy, repel, trap, or mitigate any pest, including but not limited to rodents, molds, viruses, and bacteria, FIFRA Section 2(h). EPA has interpreted devices as working through physical or mechanical means (such as electricity, light, or physical force). Examples of devices may include water or air filters, ultraviolet light systems, ozone generators, and sound generators. If a device incorporates a substance or mixture of substances to perform its intended pesticidal purpose, then it is considered a pesticide, not a device, and would require registration under FIFRA Section 3.

What are the FIFRA Requirements Applicable to Devices?

Any person who distributes or sells any device in the U.S. is expected to know and comply with applicable statutory and regulatory requirements that include, but are not limited to, the following requirements, found at 40 C.F.R. § 152.500:

- Labeling - FIFRA Section 2(q)(1) and 40 C.F.R. Part 156;
- Establishment Registration and Reporting - FIFRA Section 7 and 40 C.F.R. Part 167;
- Books and Records - FIFRA Section 8 and 40 C.F.R. Part 169;
- Establishments - FIFRA Section 9;
- Violations, Enforcement and Penalties - FIFRA Sections 12, 13, and 14;
- Imports and Exports - FIFRA Section 17;
- Child-resistant packaging - FIFRA Section 25(c)(3); and
- EPA's authority to declare devices subject to certain provisions of FIFRA - FIFRA Section 25(c)(4).

Imports

CBP regulations implement and outline requirements for submitting a completed Notice of Arrival of Pesticides and Devices (NOA) to CBP for FIFRA-regulated pesticide and devices (see Section 17(c) of FIFRA and 19 C.F.R. §§ 12.110 - 12.117). Importers must submit a separate NOA for each unique FIFRA-regulated pesticide and device in each shipment. EPA coordinates regularly with CBP to identify and refuse entry to violative pesticides and devices at ports of entry. For information on filing an EPA NOA, importers or their authorized agents can refer to the "ACE Tips for Filing EPA Pesticides," which can be found at the link below.

State Regulation of Devices

In addition to EPA, some states also regulate devices and may require registration. Compliance with FIFRA's requirements does not ensure that a device can be legally sold in those states. Please see the following for a list of state contacts:

<https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/state-and-territorial-pesticide-agencies>

Distribution or Sale of a Misbranded Device is Unlawful

Devices may not be distributed or sold if they are misbranded. A product may be considered misbranded:

1. If the label or labeling is missing the applicable elements detailed in [FIFRA Section 2\(q\)\(1\) and 40 C.F.R. Part 156](#) (e.g., Directions for Use EPA, Establishment Number).
2. If its labeling bears any statement, design, or graphic representation relative to it or its ingredients that are *false or misleading* in any particular. Labels and labeling are defined in FIFRA Section 2(p) and may include internet content (e.g., websites). 40 C.F.R. § 156.10(a)(5) provides some examples of false/misleading statements, including (but not limited to):
 - A false/misleading statement concerning the composition of the product.
 - A false/misleading statement concerning the effectiveness of the device.
 - A false or misleading statement about the value of the device for a non-pesticidal purpose.
 - A false or misleading comparison with other pesticides or devices.
 - Any statement directly or indirectly implying that the device is recommended or endorsed by any federal agency.
 - A true statement used in such a way as to give a false/misleading impression to the purchaser.
 - Label disclaimers which negate or detract from requirement label statements.
 - Non-numerical and/or comparative statements on the safety of the product.

Producers and sellers of devices are responsible for ensuring that the device performs as claimed, and that such performance claims are not false or misleading. EPA recommends that companies maintain records, with information and data, to substantiate such claims.

Devices will be considered misbranded where the labeling states or implies that the EPA establishment number, the EPA company number, or the fact that the device was produced in a registered establishment, is an EPA recommendation or endorsement. The purpose of the EPA establishment number is to identify the location where the product was manufactured or labeled, and it is required on the device label.

Although device labels are not subject to pre-market review or approval by EPA, it may be helpful to review the EPA Label Review Manual—in particular, the Labeling Claims chapter (Chapter 12) and Graphics and Symbols chapter (Chapter 16)—for claims, graphics, and symbols that EPA may consider false or misleading (See link below).

Additional Information and EPA Interpretations Impacting Devices

For instructions on requesting an EPA regulatory determination as to whether a product is a device, pesticide, or not regulated under FIFRA:

If you are uncertain about whether your product is a device, you may submit a request for a Device Determination from EPA. Instructions for submitting a request can be found at:

<https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices#obtain>

For text of FIFRA:

<https://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter6&edition=prelim>

For text of the pesticide regulations, Title 40 of the Code of Federal Regulations, Parts 150 to 189:

<https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E>

For EPA’s Pesticide Device Guide for Consumers:

<https://www.epa.gov/safepestcontrol/pesticide-devices-guide-consumers>.

For EPA’s Compliance Advisory “EPA Regulations About UV Lights that Claim to Kill or Be Effective Against Viruses and Bacteria”:

<https://www.epa.gov/sites/default/files/2020-10/documents/uvlight-complianceadvisory.pdf>

For more information on applicable device requirements:

<https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>

<https://www.epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice>

For more information on labeling requirements:

<https://www.epa.gov/pesticide-registration/label-review-manual>

<https://www.epa.gov/pesticide-labels/pesticide-labeling-questions-answers>

For more information on the filing requirements for importing and exporting devices:

Overview of import and exports requirements at <https://www.epa.gov/compliance/importing-and-exporting-pesticides-and-devices>

ACE Tips for Filing EPA Pesticides at <https://www.cbp.gov/document/publications/ace-tips-filing-epa-pesticides>

For more information on registering an EPA Pesticide Producing Establishment:

<https://www.epa.gov/compliance/pesticide-establishment-registration-and-reporting>

For submitting tips and complaints related to devices that may be in violation of FIFRA:

<https://echo.epa.gov/report-environmental-violations>

For a List of Pesticide Regulatory Consultants:

<https://www.epa.gov/pesticide-registration/list-pesticide-regulatory-consultants>

Note that the inclusion of any business in this listing does not constitute a recommendation or endorsement by EPA.

For more information on EPA’s violation disclosure policies:

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 EPA’s violation disclosure policies, including conditions for eligibility, please review EPA’s Audit Policy website at <https://www.epa.gov/compliance/epas-audit-policy>. Most violations can be disclosed and processed via EPA’s automated online “eDisclosure” system:

<https://www.epa.gov/compliance/epas-edisclosure>. Many states also offer incentives for self-policing; please check with the appropriate state agency for more information.

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. The regulated community is independently responsible for determining whether they have any FIFRA obligations.