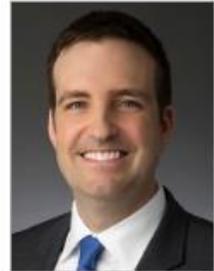


Expect EPA Scrutiny Of COVID-19 Product Claims

May 12, 2020

By Andrew Stewart, Marshall Morales and Joseph Zaleski

The dominant narrative surrounding the [U.S. Environmental Protection Agency](#) under the current administration has been deregulation and an industry-friendly enforcement environment. Environmental advocacy groups and others assert that the EPA has initiated fewer environmental civil and criminal actions and inspections since the end of the prior administration, on a consistent downward trend.[1]



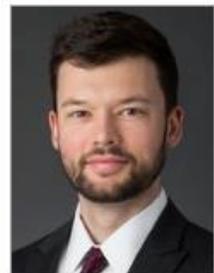
Andrew Stewart

But this is not the case in the realm of the Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA, which the EPA continues to stress as a priority area in national enforcement guidance.[2] Total penalties and total expedited settlement agreements involving pesticides in 2019 were higher than in 2015, and the number of stop-sale orders (one of the EPA's most used enforcement tools under FIFRA) in 2019 was comparable to the number in 2015.[3]



Marshall Morales

Most recently, while the EPA recently announced a plan to exercise national enforcement discretion during the COVID-19 pandemic, the agency explicitly excluded pesticide issues from its COVID-19 guidance memorandum, as FIFRA regulates substances intended to kill viruses — like the SARS-CoV-2 novel coronavirus that causes COVID-19.[4]



Joseph Zaleski

Given these trends, it more important than ever to understand the EPA's strategies and priorities for enforcing federal pesticide law. In this article, we highlight two interrelated pesticide law hot spots: the COVID-19 pandemic, and pesticide devices more generally.

Companies engaged in the development, manufacture, distribution, import or retail sale (especially online retail) of pesticide products or devices needs to keep their eyes on these

issues, and be prepared with a strategy in the event of past or current noncompliance, including mitigating chances of an enforcement action with self-disclosure through the EPA's audit policy.

FIFRA at a Glance

Congress defined "pesticide" broadly to cover, among other things, "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."^[5] This includes not only conventional pesticides — like products you would spray on fields to kill weeds or bugs — but also antimicrobial and biocidal products used on surfaces to kill microbes or viruses.

Disinfecting wipes, antimicrobial sprays and dilutable sterilizers all generally fall within the EPA's FIFRA purview. And FIFRA civil enforcement actions can easily produce six- or seven-figure penalties.

The EPA conducts premarket review of pesticide products before they can be sold in the U.S., and pesticide products must be manufactured in a registered pesticide-producing establishment — even if manufactured abroad. It is unlawful to sell or distribute unregistered pesticide products or to sell or distribute products or devices that are misbranded (e.g., selling a product with labeling or associated advertising that differs from the label registered with the EPA, or selling a device with labeling that makes false or misleading claims).^[6]

Thus, unregistered products that make claims about killing pests, including viruses, could be violating FIFRA — and retailers could unwittingly be selling products making improper pesticidal claims.

Additionally, FIFRA regulates pesticide "devices," defined as an "instrument or contrivance ... which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life."^[7] Devices come in many varieties, from water filtration systems to ultraviolet light units and bug zappers to high frequency sound generators.

Unlike with pesticide products, though, the EPA does not conduct any premarket review of devices, and device manufacturers are not required to register labels. Although not registered with the EPA, devices are still subject to prohibitions on making false or

misleading claims on labeling, are required to meet import filing requirements when imported, and must be produced in registered pesticide-producing establishments.

Companies wishing to import pesticide products or devices are required to follow a variety of protocols to ensure that [U.S. Customs and Border Protection](#) and the EPA can evaluate whether those products may enter into the stream of commerce in the U.S. Importers that do not follow these steps can have their products denied entry at the port.[8]

The EPA also has wide latitude to bring its own civil administrative enforcement actions without engaging the [U.S. Department of Justice](#) (unless the violations are criminal), and several of these administrative civil matters in recent years have resulted in seven-figure civil penalties.

FIFRA Enforcement During the COVID-19 Pandemic

Because the EPA must approve efficacy claims made by antimicrobial and disinfectant products used on surfaces to kill bacteria and viruses, the agency has played a unique role during the COVID-19 pandemic.

In late January, the EPA initiated a protocol to approve (in a limited way) antimicrobial products for use on hard surfaces as effective against the novel coronavirus. In general, the protocol allows pesticide product registrants that have demonstrated efficacy against similar, or more difficult-to-kill viruses, to make limited, preapproved claims of efficacy against an emergent pathogen — so-called "emerging viral pathogen" claims. The COVID-19 pandemic is the first time EPA has triggered this kind of emerging viral pathogen framework for claims.

In early March, the EPA published its first iteration of a list of products that it approved to make these emerging viral pathogen claims — called List N.[9] At the time of writing, List N contains 370 products, and the agency expects to continue updating this list weekly.

The EPA has also expedited review of emerging viral pathogen claims, to ensure more products are being added regularly to List N,[10] and easing the process for pesticide product manufacturers to secure alternative sources of inert and active ingredients in the event of global supply chain disruptions.[11] Any other product that purports in its label or advertising to control the novel coronavirus is by definition misbranded.

Additionally, the EPA has prioritized enforcement against spurious novel coronavirus or COVID-19 efficacy claims made by companies and individuals seeking to take advantage of the crisis. As discussed above, the agency explicitly excluded pesticide product claims and import of pesticide products from its COVID-19 enforcement discretion policy — and it also stated definitively that it intends to pursue enforcement again against entities that make false or misleading claims related to efficacy against the novel coronavirus or prevention of COVID-19.[12]

The EPA is already making good on these warnings. The U.S. Department of Justice, working in collaboration with EPA criminal investigators and other agencies, recently indicted an individual in Georgia for allegedly selling an unregistered pesticide in the form of lanyards claiming to protect the wearer from viral infections including the novel coronavirus.[13] EPA Administrator Andrew Wheeler highlighted this product, and the agency's efforts to stop importation of this product, on a recent conference call with some of the country's largest brick-and-mortar and e-commerce retailers.[14]

Importantly, the EPA has been policing novel coronavirus claims by using "desktop enforcement" — that is, reviewing claims being made through websites and e-commerce platforms. The above Georgia indictment indicates, for example, that the allegedly noncompliant products were being marketed and sold through an online auction site. Manufacturers and retailers should assume that the EPA is reviewing any coronavirus claims on websites or on internet retail platforms.

Because pesticide devices are not registered with the EPA, and because the agency does not affirmatively review device efficacy claims, pesticide device manufacturers have no means of seeking advance approval to make emerging viral pathogen claims (as they can for pesticide products). The EPA has not added any pesticide devices to List N, and it does not plan to.[15]

The only permissible basis for claiming a device's effectiveness against the novel coronavirus is confirmation by laboratory testing directly on the novel coronavirus. Some laboratories are in the very early stages of getting access to the novel coronavirus to conduct these types of tests — but it is unlikely that many (if any) pesticide devices have gone through the direct testing that would be necessary to legitimately make these types of efficacy claims.

Thus, pesticide device manufacturers and sellers should use caution with any statements that suggest a device is effective against the novel coronavirus. Even claims of efficacy against different types of human coronavirus could be construed as implied claims relating to the novel coronavirus, which would present false or misleading information to consumers.

Broader Pesticide Device Trends

This scrutiny of novel coronavirus claims is coinciding with the EPA's renewed emphasis on pesticide device enforcement more broadly.

As discussed above, devices do not go through the same premarket review and approval with the agency as pesticide products. This lack of process can cause uncertainty in the regulated community because, without affirmative review requirements, entire industries may not be aware they are manufacturing a pesticide device that must meet the requirements of FIFRA.

The EPA has been working to clarify its pesticide device regulatory regime. For example, the agency has revised its Pesticide Registration Manual chapter on pesticide devices, as well as its pesticide device guide webpage. The EPA has also issued interpretive statements related to categories of goods it considers to be regulated pesticide devices (e.g., devices used by water treatment facilities, gamma irradiation units and ultraviolet light units).[16]

Notably, the EPA has been scrutinizing product and device imports to identify potentially noncompliant pesticide devices being shipped into the country. As the deputy director of the agency's Office of Pesticide Programs recently stated, "[o]ften, the Agency becomes aware of a device through the import Notice of Arrival process which is time-sensitive." [17]

The EPA, in cooperation with U.S. Customs and Border Protection, has the authority to review pesticides entering the country, and impound noncompliant products and devices. We understand that recently, the agency has been aggressively denying admission of pesticide imports, especially devices, in order to review FIFRA compliance.

Once a device is denied admission and impounded, it will likely never enter the stream of commerce. And the importer and manufacturer will almost certainly face further scrutiny

from the EPA, which may eventually result in an enforcement action. A 2013 EPA administrative settlement involving pesticide device imports, for example, resulted in a nearly \$2.7 million civil penalty.[18]

Self-Disclosing Past Noncompliance to the EPA

For pesticide product and device manufacturers, importers, distributors and retailers that believe they may have violated FIFRA, the EPA's audit policy self-disclosure system provides a way to mitigate potential compliance risk.

The agency's self-disclosure protocol allows companies to self-report past noncompliance found through auditing, in exchange for significant penalty mitigation. The EPA currently implements the audit policy through an online portal known as eDisclosure, and while the agency screens all disclosures, it may not always follow up.

In order to take advantage of this self-disclosure program, a few threshold requirements must be met:

- The noncompliance must be discovered through an environmental audit, not a routine audit required by law. Note that the audit policy does not explicitly define what constitutes an applicable environmental audit.
- The disclosure must be voluntary, and cannot be prompted by the EPA or another regulatory agency discovering the noncompliance. This is especially important for importers where specific products have been refused admission into the country — these specific products may no longer be eligible for audit policy self-disclosure.
- The disclosure must be timely; it must be disclosed to the EPA within 21 days of discovery.

- Repeat violators cannot self-disclose. That is, if you have recently been subject to EPA enforcement actions for the same compliance issues and within certain timeframes, you will not be able to take advantage of self-disclosure.

The Path Forward

As the pandemic progresses, it seems certain that the EPA will continue to expedite approval of new pesticide products that effectively control the novel coronavirus, and take quick enforcement action against potential violators.

Although pesticide regulation and enforcement is primarily the province of the EPA, the regulated community should be aware that several states — such as California — have active state pesticide programs, and may also become involved in COVID-19-related pesticide approvals and enforcement.

[Andrew Stewart](#) is counsel, and [Marshall Morales](#) and [Joseph Zaleski](#) are associates, at Sidley [Austin LLP](#).

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

[1] EPA, Fiscal Year 2019 EPA Enforcement and Compliance Annual Results (Feb. 13, 2020), <https://www.epa.gov/sites/production/files/2020-02/documents/fy19-enforcement-annual-results-data-graphs.pdf>. Note that initiation of criminal actions saw an uptick in 2019 numbers over 2018 numbers.

[2] EPA, Office of Enforcement and Compliance Assurance National Program Guidance FY 2020-2021 (June 7, 2019), <https://www.epa.gov/sites/production/files/2019-06/documents/fy-20-21-oeca-np-guidance.pdf>.

[3] EPA presentation at the Association of American Pesticide Control Officials Spring 2020 meeting, "EPA's FIFRA Enforcement: Priorities and Recent Outcomes" (March 2020), https://aapco.files.wordpress.com/2020/03/fifra-aapco-march2020_enforcement-sullivan-3-9-20.pdf.

[4] EPA Memorandum, COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program (March 26, 2020), <https://www.epa.gov/sites/production/files/2019-06/documents/fy-20-21-oeca-np-guidance.pdf>.

[5] 7 U.S.C. § 136(u).

[6] 7 U.S.C. § 136j(a).

[7] 7 U.S.C. § 136(h).

[8] 7 U.S.C. § 136o; 19 C.F.R. §§ 12.110 - 12.117.

[9] EPA's List N is accessible here: <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>.

[10] EPA Press Release, "EPA Expediting Emerging Viral Pathogens Claim Submissions" (March 9, 2020), <https://www.epa.gov/newsreleases/epa-expediting-emerging-viral-pathogens-claim-submissions>.

[11] EPA Press Release, "EPA Continues Efforts to Help Increase the Availability of Disinfectant Products for Use Against the Novel Coronavirus" (March 26, 2020), <https://www.epa.gov/newsreleases/epa-continues-efforts-help-increase-availability-disinfectant-products-use-against>; EPA Press Release, "EPA Takes Action to Assure Availability of Disinfectant Products for Use Against the Novel Coronavirus" (March 31, 2020), <https://www.epa.gov/newsreleases/epa-takes-action-assure-availability-disinfectant-products-use-against-novel>.

[12] EPA, List N FAQ: "Will EPA take enforcement action against companies making false claims that their disinfectants work against SARS-CoV-2?", <https://www.epa.gov/coronavirus/will-epa-take-enforcement-action-against-companies-making-false-claims-their>.

[13] U.S. Department of Justice Press Release, "Georgia resident arrested for selling illegal products claiming to protect against viruses" (April 9, 2020), <https://www.justice.gov/usao-ndga/pr/georgia-resident-arrested-selling-illegal-products-claiming-protect-against-viruses>.

[14] EPA Press Release, "EPA Administrator Wheeler Talks with Retailers and Third-Party Marketplace Platforms to Discuss Steps to Protect American Consumers from Fraudulent Coronavirus Disinfectant Claims" (April 3, 2020), <https://www.epa.gov/newsreleases/epa-administrator-wheeler-talks-retailers-and-third-party-marketplace-platforms-discuss>.

[15] EPA, List N FAQ: "Why aren't ozone generators, UV lights or air purifiers on List N? Can I use them to kill the COVID-19?", <https://www.epa.gov/coronavirus/why-arent-ozone-generators-uv-lights-or-air-purifiers-list-n-can-i-use-them-kill-covid>.

[16] EPA presentation at the Association of American Pesticide Control Officials Spring 2020 meeting, "Pesticide Devices" (March 2020), <https://aapco.files.wordpress.com/2020/03/aapco-pesticide-devices-messina-final.pdf>.

[17] *Id.*

[18] In re [EMD Millipore Corp.](#), Consent Agreement and Final Order (July 30, 2013), <https://www.epa.gov/sites/production/files/2014-07/documents/emdmillipore-cafo.pdf>.

Article Link: <https://www.law360.com/articles/1271237/expect-epa-scrutiny-of-covid-19-product-claims>