

Biden EPA Continues Aggressive Enforcement Against Disinfectant Products and UV Devices Claiming to Kill Coronavirus

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One of the few areas of EPA policy continuity between the Biden and Trump eras is the aggressive enforcement attention being paid to products that claim to fight the SARS-CoV-2 *coronavirus*.

While EPA has long prioritized enforcement of the rules governing antimicrobial products (disinfectants and the like), the current pandemic has elevated that focus substantially, particularly against products that claim or suggest effectiveness in fighting *coronavirus* and other microbes. Some of the more high-profile actions over the last year have [targeted on-line sales of products](#) (often imports) that are not registered with EPA to make antimicrobial claims, as required by the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).

In a January 2021 update to a COVID-related compliance [advisory first issued in May 2020](#), EPA reiterated its aggressive enforcement stance, with an emphasis on internet product sales:

*EPA is receiving a steady stream of tips/complaints concerning potentially false or misleading claims, including efficacy claims, associated with pesticides and devices. These tips and complaints are being actively reviewed and efforts are being made to identify violative products. EPA intends to pursue enforcement against products making false and misleading claims regarding their efficacy against the coronavirus. **EPA is particularly concerned with pesticide and pesticide device products sold online on e-commerce platforms that are fraudulent, counterfeit, and/or otherwise ineffective.** EPA is also coordinating with the U.S. Department of Justice, U.S. Customs and Border Protection, and other federal partners to bring the full force of the law against those selling or otherwise distributing violative products.*

The updated EPA advisory also highlights agency concerns with products improperly claiming long-lasting anti-viral effects (so-called "residual claims" that a product "provides an ongoing antimicrobial effect beyond the initial time of application, ranging from days to weeks to months"). Such claims only are allowed if approved by EPA and "supported by acceptable studies demonstrating satisfactory residual efficacy," consistent with [agency guidance issued in October 2020](#).

EPA's updated advisory also expands on, and somewhat shifts, the agency's discussion of pesticide "devices" (e.g., UV lights, ozone generators, and other instruments that use physical or mechanical means to control pests, including viruses and other germs) that claim to kill the *coronavirus*. Unlike chemical pesticides, devices are not required to be registered by EPA and, therefore, are not

scrutinized by the agency to ensure they are safe to use or work as intended. [Note that devices must meet other EPA requirements, including being labeled with an "EPA Establishment Number" to identify the facility at which the device was produced, and not being marketed with "false or misleading" claims.] While EPA does not review efficacy data for these products, manufacturers must have on file adequate substantiation for the claims they make. Interestingly, the May 2020 advisory noted that "devices may not be able to make claims against *coronavirus* where devices have not been tested for efficacy or safety for use against the virus causing COVID-19 or harder-to-kill viruses." This language has been replaced in the January 2021 advisory with a more general reminder that

[M]aking false or misleading labeling claims about the safety or efficacy of a pesticidal devices is prohibited and could result in the issuance of a Stop Sale, Use, or Removal Order and penalties In addition, on the litigation front, EPA continues to fight two novel challenges to the scope of the agency's enforcement authority. In the first case (*Zuru LLC v. EPA*), filed in September, the company is challenging EPA's determination that its cleaning wipes are an unregistered pesticide, and blocking its importation, because the wipes contain an active ingredient found in a number of other EPA-registered disinfectants; of website statements made by third party resellers that the wipes are "disinfectants" and "kill germs"; and the product name "'Bactive' implies bacterial fighting properties."

The second case, *Tzumi Innovations v. EPA*, filed in December, similarly involves objections to EPA's designation of the company's hand wipes (typically for use on the human body and an FDA-regulated product) as an unregistered pesticide and a threatened Stop Sale, Use, Or Removal Order (SSURO). EPA filed a new brief in that case on February 3 asserting that the matter is not ripe for review and, substantively, that the wipes are properly considered pesticides because they are being marketed for use on surfaces.

Both challenges provide a reminder of the extensive scope of EPA's FIFRA authority, including over products that do not explicitly make antimicrobial claims, but imply such effectiveness through other statements or based on the presence of certain active ingredients. For a more detailed discussion, see [my prior blog post](#).

A copy of EPA's updated COVID Compliance Advisory "What You Need to Know Regarding Products Making Claims to Kill the *Coronavirus* Causing COVID-19" is available [here](#).