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## Disinfecting for COVID-19: The Role of the US Environmental Protection Agency

Coronavirus: Environmental Advisory

By [Lawrence E. Culleen](#)

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The rapid spread of COVID-19 has triggered responses from federal, state, and local government agencies and generated significant consumer and commercial interest in products that can help decontaminate surfaces to fight the spread of the virus. In light of this, there is a great temptation for companies that produce cleaning products to market their products as being effective against SARS-CoV-2 (the cause of COVID-19) when it might be present on surfaces and objects such as doorknobs, countertops, and tables. However, such businesses must be aware that these claims are regulated by the US Environmental Protection Agency (EPA) and many state agencies, and making these claims without proper EPA approval could result in an enforcement action. Here are a few things to keep in mind before making claims that a product is effective against SARS-CoV-2:

### EPA Regulates Many Antimicrobial Products as Pesticides

EPA regulates antimicrobial products (labeled as sanitizers, disinfectants, or sterilants) as pesticides when such products are intended for use on objects.<sup>1</sup> EPA shares responsibility for the regulation of antimicrobial products with the US Food and Drug Administration (FDA), which is responsible for the regulation of antimicrobial products intended for use against bacteria or viruses on or in humans or animals (such as hand sanitizers).<sup>2</sup> Depending on the claims being made on a product, the product may be regulated by EPA, FDA, or both.

### EPA Restricts Product Claims About Effectiveness Against COVID-19

EPA-regulated antimicrobial products must meet specific agency requirements before they can be marketed as effective against SARS-CoV-2. EPA has developed a list of products that it has approved for use against SARS-CoV-2 (described in further detail below). As EPA explained in its [Frequently Asked Questions](#) about this list, none of the products that appear on the list have actually been tested against SARS-CoV-2, as this is a new virus. EPA added these products to its approved list based on (1) their "demonstrated efficacy against a harder-to-kill virus" (2) their "demonstrated efficacy" against a virus similar to SARS-CoV-2; or (3) qualification for EPA's ["Emerging Viral Pathogen Claims."](#)

### Making Unapproved Claims About Effectiveness Against COVID-19 is Illegal

Marketing an antimicrobial product in a manner inconsistent with its label violates the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).<sup>3</sup> Thus, marketing an EPA-regulated antimicrobial product as effective against SARS-CoV-2 when it has not been approved by EPA for this use violates FIFRA. Recognizing that makers of EPA-regulated antimicrobial products may wish to add claims to their products about effectiveness against SARS-CoV-2, EPA has established an expedited review process for [Emerging Viral Pathogens Claims](#). EPA's [Emerging Viral Pathogens Claims](#) process is a voluntary process that allows companies to promote claims about effectiveness against emerging viral pathogens (like SARS-CoV-2) based on previous EPA-approved claims that the product is effective against harder-to-kill (e.g., "non-enveloped") viruses. Such claims can be included in "technical literature distributed to health care facilities,

physicians, nurses, public health officials, non-label-related websites, consumer information services, and social media sites."<sup>4</sup>

Notably, EPA also has the authority to allow "Emergency Exemptions" for unregistered uses of pesticides under emergency conditions.<sup>5</sup> Federal and state agencies may seek emergency exemptions from EPA requirements for registration in "emergency conditions," including when an exemption is needed to "control a pest [such as a virus] that will cause a significant risk to human health" (a "public health exemption").<sup>6</sup> A public health exemption is valid for one year.<sup>7</sup> EPA also has the authority to grant a "crisis exemption" when there is an "immediate need" to use a pesticide to control a pest.<sup>8</sup> A crisis exemption is valid for 15 days, during which time the federal or state agency seeking the exemption must file an application with EPA for another exemption (for example a public health exemption).<sup>9</sup> EPA has not yet issued any emergency exemptions relating to COVID-19.

## EPA's COVID-19 Disinfectant List

EPA has published a [list](#) of EPA-registered antimicrobial products that are "qualified for use" against SARS-CoV-2. This list was originally published on March 5, 2020, and was most recently [updated](#) on March 13, 2020. If a company has a product that is effective against SARS-CoV-2 and the product does not yet appear on EPA's list, there are a few ways for the company to get its product listed.<sup>10</sup> First, a product is eligible for inclusion on the list if it has an approved Emerging Viral Pathogens Claim for SARS-CoV-2. Second, if a product does not have an approved Emerging Viral Pathogens Claim for SARS-CoV-2 (and the owner of the product is not applying for one), the owner of the product may seek inclusion on EPA's list by [emailing](#) EPA's disinfectant team. The Centers for Diseases Control also [cross references](#) EPA's list of products authorized for such uses.

## A Note Regarding the Role of the States in Regulating Antimicrobial Product Claims

All 50 states have laws requiring the registration of pesticide products that will be used or sold within their states (including antimicrobial products). Such states also require notification of state agencies when changes are made to the federal and state-registered pesticide product labels. For example, New York requires the [registration](#) of pesticide products, and also requires makers of these products to [notify](#) the state's Department of Environmental Conservation when changes are made to the label of a pesticide product. Notably, New York has created its own [list](#) of EPA-approved and New York State-registered antimicrobial products that are considered to be effective against SARS-CoV-2. California similarly requires the [registration](#) of pesticide products and [notification](#) to the state's Department of Pesticide Registration when a change is made to the label of a pesticide product (such as an antimicrobial product), and has provided a [link](#) to EPA's approved list.

## Conclusion

EPA has indicated that the agency and its state partners will take enforcement action against companies that make unapproved claims about a product's effectiveness against SARS-CoV-2.<sup>11</sup> EPA has noted that its expedited review process for products effective against SARS-CoV-2 does not "eliminate[]" the need to comply with FIFRA.<sup>12</sup> Thus, as companies seek to promote consumer and commercial users' awareness of products effective against SARS-CoV-2, they must also ensure compliance with federal and state regulatory requirements.

<sup>1</sup> 40 C.F.R. Part 152.

<sup>2</sup> 40 C.F.R. § 152.6(c)-(d).

<sup>3</sup> 7 U.S.C. §§ 136, 136j.

<sup>4</sup> Press Release, U.S. Env'tl Protection Agency, [Coronavirus Cases Trigger EPA Rapid Response](#) (Jan. 29, 2020).

<sup>5</sup> 40 C.F.R. Part 166.

<sup>6</sup> 40 C.F.R. § 166.2(c).

<sup>7</sup> *Id.* § 166.28(a).

<sup>8</sup> *Id.* § 166.2(d).

<sup>9</sup> *Id.* § 166.45(b).

<sup>10</sup> U.S. Env't'l Protection Agency, [Frequently Asked Questions About List N: Disinfectants for Use Against SARS-CoV-2](#) (Mar. 13, 2020).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*