The US Environmental Protection Agency (US EPA) has issued a list of nearly 300 disinfectants that have qualified for use against SARS-CoV-2, the coronavirus that causes COVID-19. The list can be found here. According to US EPA, the disinfectants on the list have not been tested specifically against SARS-CoV-2, but they are expected to be effective against the virus because they have been tested and proven effective on either a harder-to-kill virus or against another human coronavirus similar to SARS-CoV-2.

In addition to publishing the list of disinfectants qualified for use against SARS-CoV-2, US EPA has “activated” its Emerging Viral Pathogens Guidance for Antimicrobial Pesticides, which sets forth an accelerated process for reviewing and adding products to the list, as well as allowing a registrant to make a claim that its registered disinfectant may be used against SARS-CoV-2. Under the guidance, which was issued in 2016 during the Obama Administration, US EPA is giving expedited
review to requests by pesticide registrants seeking to make emerging viral pathogen claims for surface disinfectants that already are registered with US EPA. The expedited review process potentially can reduce the review time to roughly 14 days, compared to the 90-days typically required to review claims like these. At present, however, US EPA is giving expedited review only to claims for registered surface disinfectants that do not require review of new efficacy data.

Any registrant seeking expedited approval from US EPA to make a claim for SARS-CoV-2 for its already-registered disinfectant should include as part of its submission to the agency a cover letter that includes the following information:

- a subject line that clearly indicates “Emerging Viral Pathogen Claim for SARS-CoV-2”;
- a request to make emerging a viral pathogen claim;
- a description of how the product meets the eligibility criteria for use against one or more categories of viral pathogens consistent with the Emerging Viral Pathogens Guidance;
- identification of the virus(es) from the product label that support the emerging viral pathogen claim and the study ID number (MRID) that supports the claim;
- an up-to-date matrix (US EPA Form 8570-35); and
- a request to add the Terms of Registration outlined in Attachment I of the Emerging Viral Pathogens Guidance.

US EPA also is directing registrants to submit a revised master label with a separate section for emerging viral pathogen claims that includes the generic claim statements identified in Attachment I of the Emerging Viral Pathogens Guidance. All materials should be submitted via US EPA’s central data exchange (CDX) portal. After the application has been submitted via the CDX portal, the registrant should send an email to disinfectantslist@epa.gov with the CDX tracking number, so that US EPA will know that expedited review is requested for the submission.

Even if a company does not wish to make an emerging viral pathogen claim for its product, a company can request that US EPA add its product to the agency’s EPA’s list of qualified disinfectants if the company is the primary registrant of the disinfectant. In that case, the company should send an email to disinfectantslist@epa.gov and state the following in the subject line of the email: “Include Product(s) on List [Insert list Identifier]; [Registration #(s)].” In the body of the email, the company should provide its name, the registration number of its disinfectant, and the primary brand name(s) of the product(s). US EPA will review the request, and “if appropriate,” the agency will add the disinfectant to the list.

Companies must be very careful about any representations they make about the effectiveness of their products against COVID-19. US EPA has stated that it will take action against any company that makes a false claim that its disinfectant works against SARS-CoV-2, including issuing a stop sale order and seeking penalties. Additionally, the US Federal Trade Commission (US FTC) and the US Food and Drug
Administration (US FDA) have sent warning letters to several companies for allegedly selling unapproved products that may violate federal law by making deceptive or scientifically unsupported claims about their ability to treat COVID-19.

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