Alert

August 31, 2020

COZEN O'CONNOR

Is EPA's Emergency Approval of Long-lasting Disinfectant a Game Changer?

Related Practice Areas

- Environmental Regulatory & Due Diligence

The U.S. Environmental Protection Agency (USEPA) took the unusual step of allowing a new COVID-19 disinfectant to bypass the normal review and registration process under an emergency exemption issued August 24. The onset of the COVID-19 pandemic has caused businesses to re-evaluate many of their needs and operational capacities, particularly in relation to the disinfection of commonly touched surfaces. While increased cleaning and hand washing provide some benefits, the limitations of these conventional methods becomes particularly pronounced in heavily trafficked areas and places where frequent touching are operational necessities, such as mass transit systems or large public indoor spaces like airports or entertainment venues. Last week, one of the first products that attempts to address these problems through longer-term surface disinfection received a limited use approval, potentially expanding the available arsenal to assist in reducing the risks associated with surface spread.

On August 24, EPA's Pesticide Program issued an "Emergency Exemption" under Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to the state of Texas to permit the use of a chemical disinfectant product that claims to effectively kill viruses on surfaces for up to seven days after application (including the virus causing COVID-19: SARS-CoV-2). The product, manufactured by Allied BioScience, utilizes a silane quaternary ammonium salt-based antimicrobial agent that has previously been approved as a static antibacterial and fungicidal product for long term protection against odor and stain causing microbes, as well as for commercial applications for material preservation. This, however, marks the first approval for antiviral applications. In addition, despite the approval of these products and USEPA's emergency exemption, environmental groups have raised some concerns about the potential human health impacts for sensitive individuals caused by the broader use of these commercial-grade products in high touch areas.

Under FIFRA, all virucidal pesticide products must be registered and must have demonstrated to USEPA's satisfaction that they are able to control the target pest and will not cause unreasonable adverse effects to human health or the environment when properly used. FIFRA has very limited exceptions to the requirement of registration before public health disinfectants (or pesticide products generally) can be lawfully marketed. Section 18 allows USEPA to exempt state agencies from these requirements to address emergency conditions. Under this type of exemption, USEPA authorizes limited use of a specific pesticide product in a defined geographic area for a limited period of time. According to USEPA, no other applications for Section 18 emergency exemptions have been received in connection with the COVID-19 pandemic.

The emergency exemption allows the product here to be used as a virucidal agent for indoor use on non-porous, non-food contact surfaces, but is limited to applications within the state of Texas for use in i) 27 aircraft and airport facilities owned and operated by American Airlines, and ii) two clinics managed by Total Orthopedics Sports & Spine Clinic. The product must further be applied by specifically trained applicators with significant personal protective equipment, under the direct oversight of both Allied BioScience and the Texas Department of Agriculture. It must be applied to pre-cleaned and disinfected surfaces with an electrostatic sprayer to form a coat on affected surfaces. The product also must be applied in unoccupied indoor areas and must be allowed to dry for at least 10 minutes prior to re-entry.

In response to past novel viruses that affect public health, USEPA developed the Emerging Viral Pathogen Program in 2016, a process whereby it could quickly assess whether existing data against viruses could be used to determine effectiveness against SARS-CoV-2. As a result, USEPA has developed an extensive list of disinfectants fully approved for claims against the virus, known

widely as “List N.” At present, List N includes 486 approved products, including both long-registered products and those newly approved for the market. This newly authorized “emergency use” active ingredient is contained in about 61 registered antimicrobial products, but none are approved as virucides nor are included on List N. While numerous other products on List N provide for “contact times” of up to 30 minutes, this product represents the first long-lasting microbiostatic product for use against COVID-19.

States other than Texas could work with this applicant or with others to apply for emergency exemptions under Section 18, which could involve different disinfectants and different use terms and conditions. In any event, it should be relatively easy for other states to obtain emergency exemptions similar or identical to this one.

Whether and how quickly additional USEPA actions will broaden the availability of products making claims of longer-term protection on surfaces will depend mostly on the quality and clarity of the data supporting the claims of longer-term protection of surfaces from either the SARS-Cov-2 virus itself or other, harder to kill viruses. USEPA will also have to determine that there are no unreasonable adverse effects associated with the dosage, electrostatic application method, or any other aspects of the conditions of use. Depending on the availability of existing data on this active ingredient, this determination may be straightforward, but it also could raise novel issues.