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EPA Authorizes Anti-Monkeypox Claims for Pre-Designated Disinfectant Products

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What Happened: EPA activated its Emerging Viral Pathogens guidance to permit limited claims that certain registered pesticides are effective against the monkeypox virus.

Who's Impacted: Manufacturers and distributors of disinfectant products that are pre-qualified to make Emerging Viral Pathogens claims or that are potentially effective against the monkeypox virus.

What Should They Consider Doing in Response: Consider adding anti-monkeypox efficacy claims to permitted product labeling for eligible products.

In response to the recent identification of multiple clusters of monkeypox in North America and Europe and a confirmed case of that disease in Massachusetts, the U.S. Environmental Protection Agency ("EPA") is activating a limited procedure that allows eligible disinfectant product manufacturers to publicly communicate certain efficacy claims against the monkeypox virus.

Like the SARS-CoV-2 virus that emerged in late 2019, the monkeypox virus belongs to a group of "enveloped" viruses that are more susceptible to disinfectants than other types of viruses. With its May 23, 2022 announcement, EPA indicated that registrants with a pre-qualified "emerging viral pathogen designation" can now include a statement indicating efficacy "against viruses similar to monkeypox virus" in certain product labeling and authorize use against that virus.

The approved statement may be made in product technical literature distributed to health care facilities, physicians, nurses, and public health officials; non-label-related websites; consumer information services; and social media sites. The policy does not permit registrants to add the efficacy statement to product labels themselves.

EPA has also published a new List Q of all registered disinfectant products currently approved for use against emerging viral pathogens ("EVP"). All products with EVP claims have been tested against

viruses that are more difficult to kill than monkeypox and may now include anti-monkeypox statements in product literature consistent with EPA policy. Such claims will be permitted through May 2023.

A. Background

Disinfectants, sanitizers, and other substances intended for use on objects and surfaces against microorganisms are considered antimicrobial pesticides and cannot be sold or distributed unless they are first registered by EPA under the Federal Fungicide, Insecticide, and Rodenticide Act ("FIFRA"). EPA considers antimicrobial pesticides intended to control microorganisms that pose a threat to human health to be "public health" products, and any claims for use against a specific public health pathogen must be supported by efficacy data reviewed by EPA.

However, when emerging viral pathogens like the monkeypox virus arise, few if any EPA-registered disinfectants usually specify use against them, and it can be very difficult for manufacturers to test and assess product efficacy promptly to add these viruses to existing product registrations. Under the Pesticide Registration Improvement Extension Act of 2018 ("PRIA-4"), EPA's review of a request to add a new use to an existing registered antimicrobial pesticide can take a year or more.

B. Emerging Viral Pathogen Designation

Accordingly, in August 2016, EPA developed a voluntary process for registrants of certain hospital, healthcare, or broad-spectrum disinfectant products to begin seeking advance authorization that would allow a registrant—in the event of a future human or animal disease outbreak caused by an emerging virus—to communicate that its product may be used against the emerging virus. For registered disinfectants meeting EPA's criteria, the Agency created an opportunity at any time before an outbreak for manufacturers to obtain emerging viral pathogen designation.

Under this process, an eligible product registrant can submit a request to EPA for expedited 90-day (or "fast-track") review under FIFRA sec. 3(c)(3)(B)(ii), or as a label amendment request under PRIA-4 (associated with a four-month review period). Under either scenario, the request must explain why the product meets EPA's criteria for use against a particular viral pathogen group (i.e., enveloped viral pathogens; large, non-enveloped viral pathogens; or small, non-enveloped viral pathogens). Once approved by EPA, the designated statement is added to the product's master label as a "non-label claim" and permitted only when EPA's emerging viral pathogen conditions are met.

C. Product Claims Against Monkeypox Virus

Following EPA's recent announcement, a pre-qualified registrant may now use the emerging viral pathogen statement in off-label communications to inform the public of its product's efficacy against the monkeypox virus. Note that EPA's approval in individual cases may include additional terms and conditions further restricting how the designated statement may be communicated.

Importantly, EPA's action applies only to registered disinfectants that have been pre-qualified under the 2016 process, as listed on EPA's List Q. Manufacturers and other stakeholders should expect EPA to closely monitor the use of anti-monkeypox claims in connection with all pesticide products. This includes unregistered pesticide products distributed under FIFRA's "minimum risk" exemption, which prohibits any claims to control microorganisms that pose a threat to human health. If a

purported minimum risk pesticide is labeled or marketed as effective against any such pathogen, it must be registered with EPA.

Similarly, EPA does not typically review efficacy data for pesticidal devices prior to their distribution or sale. Nevertheless, a device may be “misbranded”—and thus unlawful to be marketed—if its labeling or other marketing materials include general or specific efficacy claims that are “false or misleading in any particular.” Some devices, such as air purifiers, have been marketed as effective against coronavirus particles, and the producers or sellers of any such devices are responsible for ensuring that their products perform as claimed.

EPA maintains information and guidance regarding its emerging viral pathogen policy and current activations of that policy on its website.

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