

Got COVID-19 “Claims”: Recent US EPA Enforcement under FIFRA Emphasizes Compliance Demands on Pesticide Product Supply Chains, especially for Products Claiming to be Effective against Coronavirus

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In the age of COVID-19, demand for surface wipes, sprays and similar products is at record levels. Retail stores have struggled to keep supplies stocked and shelves may once again be emptied when the winter flu season arrives. If schools and businesses reopen concurrently, the prospects of securing these products becomes even bleaker, which may re-fuel consumer stockpiling. To meet this surging demand, manufacturers have ramped up production and new entrants are pouring into this market space in unprecedented numbers. Supply chains are already stressed and further straining is expected to continue.

Cleaning products that claim to kill SARS-CoV-2, the coronavirus that causes COVID-19, hold a rarified position in this already blazing hot market. With this competitive advantage comes increased government scrutiny. Inclusion of coronavirus claims on a surface cleaner’s label necessitates EPA approval and registration under the federal pesticide law known as the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). While EPA is working tirelessly to expedite these approvals, leading to the growth of products on EPA’s coveted [List N](#) of approved COVID-19 Disinfectants, the Agency is also keeping a watchful eye on the marketplace and instituting FIFRA enforcement actions that reiterate the need for every party in a pesticide product’s supply chain to ensure compliance with FIFRA’s detailed and expansive requirements, as highlighted by the following examples:

- On June 29, 2020, Rong Sun, a/k/a Vicky Sun, was sentenced in federal district court in the Northern District of Georgia after pleading guilty to selling an unregistered pesticide through eBay that she claimed would help protect individuals from viruses. The pesticide was marketed as “Virus Shut Out” and “Stop The Virus.” Sun was sentenced to 24 months’ incarceration and ordered to pay a \$659 fine.
- On August 4, 2020, Matt Shumaker was sentenced in federal district court in the Northern

District of Georgia after pleading guilty to selling a misbranded pesticidal device by engaging in a scheme to defraud by soliciting Georgia residents with false claims that a product called “Beyond Guardian Air” air purifier kills every major viral and bacterial infection, including the COVID-19 coronavirus disease, in the home. Shumaker was sentenced to serve 24 months of probation and pay a \$9,300 fine.

- On October 8, 2020, EPA issued a [Compliance Advisory](#) stressing that ultraviolet (UV) lights making claims to kill or mitigate coronavirus (or other pests) are subject to FIFRA requirements for pesticide devices.
- On October 15, 2020, EPA Region 2 published a [press release](#) noting the issuance of 29 Advisory Letters and 8 Notices of Warnings to entities in New York and New Jersey for pesticide products and devices making unsubstantiated claims of efficacy against coronavirus. Region 2 also prevented 52 imports of illegal pesticides in New York, New Jersey and Puerto Rico.
- Also on October 15, 2020, EPA Headquarters announced a \$7 million settlement to resolve alleged violations for imports of an unregistered pesticide. While the pesticide at issue was not making coronavirus claims, the extent of the FIFRA penalty, determined on a per violation basis, serves as a stark reminder of the need to comply with FIFRA.

Pesticides are tightly and comprehensively regulated by EPA as a niche sector of the chemical industry under the authority of FIFRA. ^[1] Under FIFRA, EPA regulates the import, manufacture, distribution, sale and use of pesticides and pesticide products. FIFRA defines a “pesticide,” in part, as “any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest.” ^[2] In turn, “pests” are defined to include bacteria, fungi, viruses or other microorganisms, in addition to insects, weeds and rodents. ^[3] Whether a chemical substance requires registration as a pesticide depends on whether it is *intended* to control pests. EPA considers a substance to be intended to control pests using three separate tests that examine whether: (1) the product’s label or other marketing material contain “pesticidal” claims, (2) the product contains an active ingredient with no significant commercial use except as a pesticide, and (3) the seller or distributor knows or should know that the product will be used as a pesticide. ^[4]

Generally, cleaning agents for inanimate surfaces are not considered pesticides unless the products are promoted either explicitly or implicitly as having the ability to destroy or repel pests, including microorganisms. ^[5] Key “pesticidal” terms that subject cleaning products to FIFRA include “sanitize,” “disinfect,” or “sterilize,” among others. Products such as hand sanitizers, antiseptic washes and antibacterial soaps that are applied to the skin, and other products ingested by humans to kill bacteria or germs inside the body are not regulated by EPA under FIFRA. Instead, these products are regulated by the Food and Drug Administration under the Federal Food, Drug and Cosmetic Act. ^[6]

Registration is the core of the FIFRA regulatory scheme. With limited exception, FIFRA and its implementing regulations require that each individual pesticide product be separately registered before the product may be *distributed or sold* in the US ^[7] The term “distribute or sell” is broadly defined as “to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver.” ^[8] Pesticides under FIFRA can include technical grade active ingredients^[9], manufacturing use products ^[10] and end-use products. ^[11] A registration is a license to a specific company to sell or distribute a particular product with an EPA-approved label. ^[12]

Due to FIFRA's stature as a strict liability statute, each and every party in a pesticide product's supply chain – including pesticide registrants, contract manufacturers, supplemental distributors, retailers and others – should institute FIFRA compliance strategies to ensure they are not selling or distributing an unregistered pesticide product. These entities also need to avoid selling or distributing any registered product that is misbranded, adulterated, makes unapproved claims, or differs in composition from the formulation approved by EPA as part of the pesticide's registration.^[13]

Ensuring compliance with FIFRA's myriad requirements often requires an elaborate journey through EPA's byzantine and arcane regulations, which have been supplemented by decades of guidance and policy issued in the form of Pesticide Registration Notices, the Pesticide Registration Manual, the Label Review Manual, the FIFRA Inspection Manual, fact sheets, frequently asked question documents, and enforcement memoranda, penalty policies and model settlement documents. Such a journey is a minefield full of traps for the unwary. Nonetheless, recent EPA enforcement actions against parties throughout a pesticide product's supply chain, including distributors and retailers, highlight that it is a journey that must be taken, particularly as a rush of products claiming to kill coronavirus race to fill retail shelves for the indefinite future. Companies should proceed carefully and seek assistance from outside counsel as necessary.

[1] 7 U.S.C. § 136 et seq.

[2] FIFRA § 2(u), 7 U.S.C. § 136(u).

[3] FIFRA § 2(t), 7 U.S.C. § 136(t).

[4] 40 C.F.R. § 152.15.

[5] See U.S. EPA, Determining if a Cleaning Product is a Pesticide under FIFRA, available at <https://www.epa.gov/pesticide-registration/determining-if-cleaning-product-pesticide-under-fifra>.

[6] See 40 C.F.R. § 152.6(c) and (d) (EPA excludes from the definition of “pest” microorganisms found in cosmetics, drugs, on humans or animals or in processed food).

[7] See FIFRA § 3(a), 7 U.S.C. § 136a(a); § 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A); 40 C.F.R. § 152.15; see also *In re Sultan Chemists, Inc.*, 9 E.A.D. 323 (EAB Sept. 13, 2000) (noting that a pesticidal solution in liquid form, as well as a towelette, spray and wand composed of the liquid solution, were each discrete pesticide products requiring independent registration).

[8] FIFRA § 2(gg); 40 C.F.R. § 152.3.

[9] See 40 C.F.R. § 152.3 (defining “active ingredient” as “any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA...”).

[10] See 40 C.F.R. § 152.3 (defining “manufacturing use product” as “any pesticide product that is not an end-use product.”).

[11] See 40 C.F.R. § 152.3 (defining “end use product” as “any pesticide product whose labeling (1) includes directions for use of the product (as distributed or sold, or after combination by the user with

other substances) for controlling pests or defoliating, desiccating, or regulating the growth of plants, and (2) does not state that the product may be used to manufacture or formulate other pesticide products.”).

[12] See 40 C.F.R. § 152.43 (noting that a product must have a single, defined composition, although EPA may approve a basic formulation and one or more alternate formulations with certain specific limits of variation).

[13] See FIFRA §§ 12(a)(1)(B), (C) and (E), 7 U.S.C. § 136j(a)(1)(B), (C) and (E).

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