Case No. 21-70719

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK, BEYOND PESTICIDES, CENTER FOR BIOLOGICAL DIVERSITY, ENVIRONMENTAL CONFEDERATION OF SOUTHWEST FLORIDA, FARMWORKER ASSOCIATION OF FLORIDA, FARMWORKER JUSTICE, NATURAL RESOURCES DEFENSE COUNCIL, INC., AND UNITED STATES PUBLIC INTEREST RESEARCH GROUP

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND MICHAEL S. REGAN, in his official capacity as Administrator of the United States Environmental Protection Agency,

Respondents.

PETITION FOR REVIEW
of a final order of the U.S. Environmental Protection Agency

BRIEF OF PETITIONERS

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INTRODUCTION

"Antibiotics save lives."[1] They are an essential tool in modern medicine, allowing people to fight a wide range of infections that would otherwise be untreatable. But antibiotics are not fail-safe. Any time antibiotics are used, resistant bacteria may survive. Over time, the repeated use of antibiotics leads to growing populations of resistant bacteria that become harder and harder to kill. Antibiotic resistance "jeopardizes" advancements in healthcare, CDC Antibiotic Report 8, and adds "considerable and avoidable costs to the already overburdened U.S. healthcare system," 1-ER-40. "Antibiotic resistance can affect any person, at any stage of life," CDC Antibiotic Report 8, and "has been found in every U.S. state and in every country across the globe," *id*. at vi. Increased use—and misuse—of antibiotics risks compromising their utility for human medicine.

[1] Ctrs. for Disease Control & Prevention (CDC), Antibiotic Resistance Threats in the United States 5 (2019) [hereinafter "CDC Antibiotic Report"], https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.

This case centers on the failure of the U.S. Environmental Protection Agency (EPA or "the Agency") to safeguard the efficacy of antibiotics for use in human medicine. In 2021, EPA registered streptomycin—an antibiotic that the U.S. Food and Drug Administration (FDA) classifies as "highly important" to human medicine—for use as a pesticide on citrus groves across the country ("the Registration"). The Registration greenlit the largest use ever of an antibiotic in plant agriculture, authorizing an 18-fold increase in the amount of streptomycin used on crops each year. *See* 3-ER-290. Hundreds of thousands of pounds of streptomycin can now be released into the environment annually, threatening to accelerate what the CDC has recognized as a "crisis" of antibiotic resistance. CDC Antibiotic Report 8.

Despite the unprecedented scale of the approval, EPA forged ahead with an inadequate analysis of the Registration's effects on public health and the environment. Specifically, EPA overlooked how airblasting streptomycin—that is, using large industrial fans to spray the antibiotic onto citrus groves—may contribute to the spread of antibiotic resistance

through environmental pathways like air, water, and soil. The Agency also dismissed the risk that exposures to streptomycin will make farmworkers vulnerable to more antibiotic-resistant infections, ignoring significant, uncontroverted evidence that personal-protective-equipment (PPE) requirements will fail to protect many workers. And as for streptomycin's environmental effects, EPA largely ignored potential harm to pollinators and to endangered and threatened wildlife.

Compounding these errors, the Agency registered streptomycin without substantial evidence that the antibiotic is even effective for its intended use on citrus. The diseases affecting citrus plants pose serious challenges to growers, and EPA failed to adequately consider whether streptomycin could offer meaningful protection from those diseases. As a result, despite unstudied dangers and unproven benefits, this medically important antibiotic is now available for widespread use in groves across the country. In the absence of a full assessment of streptomycin's effects, its continued use as a pesticide puts both people and imperiled species at risk.

EPA's registration of streptomycin violated the Agency's duties under both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Endangered Species Act (ESA). Accordingly, Petitioners respectfully request that the Court remand and vacate the unlawful Registration.

STATEMENT OF JURISDICTION

This Court has jurisdiction under FIFRA, which provides for review in the courts of appeals of "any order issued by the Administrator following a public hearing." 7 U.S.C. § 136n(b). Petitioners are challenging EPA's final orders registering streptomycin for unconditional use on citrus. 1-ER-3 to -28 (end-use product); 1-ER-29 to -32 (manufacturing use product); *see* 1-ER-33 to -53 (Final Registration Decision). EPA issued the orders "following a public hearing," 7 U.S.C. § 136n(b), because the Agency first solicited and reviewed public comments. *See United Farm Workers of Am., AFL-CIO v. Adm'r, EPA*, 592 F.3d 1080, 1082-84 (9th Cir. 2010); 3-ER-264 to -283 (Proposed Registration Decision); 3-ER-377 (soliciting public comment on Proposed Registration Decision); 3-ER-263 (extending

comment period); 2-ER-140 to -202 (responding to comments). Petitioners were "part[ies] to the proceedings" before EPA and are "adversely affected" by EPA's orders registering streptomycin. 7 U.S.C. § 136n(b); *see* 2-ER-203 to -249 (Petitioners' comments).

Petitioners have standing to challenge the Registration because the interests they seek to protect are germane to their organizational purposes, this litigation does not require their members' individual participation, and their members would have standing to sue in their own right. *See Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000); *see also Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 909-12 (9th Cir. 2020) (holding that organizations had associational standing to challenge pesticide registration under FIFRA and the ESA).

First, protecting public health and the environment—including preserving the efficacy of antibiotics, safeguarding farmworkers' health, and defending imperiled species—is germane to Petitioners' organizational purposes. *See* Trujillo Decl. ¶¶ 7-8 (ADD 255); Burd Decl. ¶¶ 4-14 (ADD 132-38); Feldman Decl. ¶¶ 4-15 (ADD 109-16); Ayech Decl. ¶¶ 5, 9-11 (ADD

177, 179-80); Economos Decl. ¶¶ 4-9 (ADD 214-17); Madaras Decl. ¶¶ 5-9, 11 (ADD 80-83). Second, neither the claims presented nor the relief requested—remand and vacatur of the Registration—require "the participation of individual members in the lawsuit." *Friends of the Earth*, 528 U.S. at 181. Third, Petitioners' members would have standing to sue in their own right because they suffer injuries that are fairly traceable to the Registration and likely to be redressed by a favorable decision. *See id.* at 180-81.

Petitioners' members have suffered procedural injuries from EPA's misapplication of FIFRA's procedural equirements for pesticide registration and the Agency's failure to support with substantial evidence its determinations that the Registration complied with those requirements. *See Nat'l Fam. Farm Coal.*, 966 F.3d at 909. In addition, Petitioners' members have suffered procedural injuries from EPA's nonperformance of the ESA's consultation requirements. *See id.* at 911. FIFRA's and the ESA's procedures are "designed to protect" Petitioners' members' "threatened concrete interest[s]" in their health and in using and enjoying the environment. *Id.* at

910 (quoting *Salmon Spawning & Recovery All. v. Gutierrez*, 545 F.3d 1220, 1225 (9th Cir. 2008)). FIFRA's "registration standards" are "safeguards . . . to ensure that approved pesticides do not cause adverse effects on the environment," *id.* at 909, including human health, *see* 7 U.S.C. § 136(bb); and the ESA's "procedures are designed to advance the ESA's overall goal of species preservation," *id.* at 911 (internal quotation marks omitted).

EPA's approval of streptomycin in violation of FIFRA's registration standards creates "a credible threat," *id*. at 909 (internal quotation marks omitted), that Petitioners' members who live, work, or recreate near citrus groves will acquire antibiotic-resistant infections. *See* Falconer Decl. ¶¶ 3-5, 12-13 (ADD 121-22, 125-26); Ayech Decl. ¶¶ 15-23 (ADD 181-84); Duggan Decl. ¶¶ 3, 5, 7-18 (ADD 194-99); McCollom Decl. ¶¶ 29-30 (ADD 244); Gordon Decl. ¶¶ 11-14 (ADD 250-51); Graham Decl. ¶¶ 10-41, 2-ER-61 to -83. It also threatens to intensify the burdens on Petitioners' members who treat farmworkers at medical clinics by increasing the risk that those farmworkers will be infected by antibiotic-resistant bacteria while working in citrus groves. *See* Galvez Decl. ¶¶ 10-21 (ADD 99-105). Further, EPA's

violations of FIFRA's and the ESA's procedures in registering streptomycin threaten harm to pollinators and endangered mammals found near citrus groves, and thereby injure Petitioners' members who photograph and observe those species. *See* Anderson Decl. ¶¶ 2-30 (ADD 140-58); Celano Decl. ¶¶ 2-16, 18-23 (ADD 160-74); Ayech Decl. ¶¶ 35-40 (ADD 188-90); McCollom Decl. ¶¶ 12-25 (ADD 236-42).

Petitioners' members' injuries are fairly traceable to EPA's violations of FIFRA and the ESA because there is a "reasonable probability" that EPA would have denied or limited the Registration had the Agency conducted a proper analysis under each of these statutes. *Nat'l Fam. Farm Coal.*, 966 F.3d at 910 (internal quotation marks omitted). And Petitioners' members' injuries are redressable by a favorable court decision because an order directing EPA to comply with the procedures required by FIFRA and the ESA "*may* influence the agency's ultimate decision" on remand. *Id.*; *see also NRDC v. EPA*, __ F.4th __, Nos. 20-70787, 20-70801, 2022 WL 2184936, at *16 (9th Cir. June 17, 2022) (holding that petitioners satisfied redressability prong of standing where "EPA might have required more mitigation

efforts had the agency completed an [ESA] effects determination"). Petitioners thus have standing to challenge streptomycin's registration.

Finally, the petition for review is timely and venue is proper in this Court because Petitioners filed their petition "in the United States court of appeals for the circuit wherein [Petitioners] reside[] or ha[ve] a place of business, within 60 days after the entry of [the challenged] order." 7 U.S.C. § 136n(b). EPA's final orders registering streptomycin for use on citrus were signed on January 12, 2021, and entered fourteen days later, on January 26, 2021. *See* 1-ER-3 to -5; 1-ER-29 to -30; 40 C.F.R. § 23.6. Petitioners petitioned for review of that order 59 days later, on March 25, 2021. *See* ECF No. 1-4. And Petitioners have offices within the Ninth Circuit, including in Arizona, California, and Montana. Burd Decl. ¶ 3 (ADD 131); Madaras Decl. ¶ 10 (ADD 83); Trujillo Decl. ¶ 5 (ADD 254).

ISSUES PRESENTED

I. Did EPA violate FIFRA when it concluded, based on an inadequate analysis of streptomycin's (1) risks to human health from antibiotic resistance; (2) risks to pollinators; and/or (3) purported benefits, that the

Registration would not cause "unreasonable adverse effects on the environment"?

II. Did EPA violate the ESA—as it concedes it did—by registering streptomycin without making a determination whether the Registration "may affect" any endangered or threatened species or those species' critical habitats?

III. Should the Court vacate the Registration upon a ruling that EPA violated FIFRA and/or, as the Agency concedes, the ESA?

STATUTORY AND REGULATORY FRAMEWORK

I. FIFRA

Under FIFRA, any pesticide must be "registered" by EPA before it can be sold or distributed in the United States. 7 U.S.C. § 136a(a). To register a new pesticide, or amend an existing pesticide registration, EPA must first determine that the pesticide "will perform its intended function without unreasonable adverse effects on the environment," and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

Id. § 136a(c)(5)(C), (D); *see* 40 C.F.R. §§ 152.112(e), 152.44; *Nw. Coal. for Alternatives to Pesticides v. EPA*, 544 F.3d 1043, 1045 (9th Cir. 2008). FIFRA defines "unreasonable adverse effects on the environment" to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb).

Before granting unconditional registration of a pesticide under § 136a(c)(5), EPA must review "all relevant data in the possession of the Agency" and conclude "that no additional data are necessary" to make the required determinations. 40 C.F.R. § 152.112(b), (c); *see Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 528 (9th Cir. 2015). While EPA's regulations set forth data that are generally required for pesticide registration, *see* 40 C.F.R. pt. 158; *id*. § 158.1(b)(1), if those data are "not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed," *id*. § 158.75. "Unconditional registration necessarily

requires sufficient data to evaluate the environmental risks." *Pollinator Stewardship Council*, 806 F.3d at 523.

II. The ESA

The ESA is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 180 (1978). The Act "affords endangered species the 'highest of priorities' in assessing risks and benefits." *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005) (quoting *Tenn. Valley Auth.*, 437 U.S. at 174), *abrogated on other grounds as recognized in Cottonwood Env't L. Ctr. v U.S. Forest Serv.*, 789 F.3d 1075 (9th Cir. 2015). Its text reveals "a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies." *NRDC*, 2022 WL 2184936, at *14 (quoting *Tenn. Valley Auth.*, 437 U.S. at 185).

Section 7 is "[t]he heart of the ESA." *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 495 (9th Cir. 2011). It requires federal agencies, "in consultation with and with the assistance of" the U.S. Fish and Wildlife

Service and the National Marine Fisheries Service ("the Services"),[2] to "insure" that any action they authorize or carry out "is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat of such species." 16 U.S.C. § 1536(a)(2); *see also id*. § 1532(5)(A) (defining "critical habitat").

The consultation process begins when, "[a]t the earliest possible time," the federal agency proposing to take an action makes an "effects determination"; that is, the agency "assesses whether [the] proposed action 'may affect' an endangered or threatened species or its critical habitat." *NRDC*, 2022 WL 2184936, at *14 (quoting 50 C.F.R. § 402.14(a)). "May affect" is "a 'relatively low' threshold." *Karuk Tribe v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (quoting *Cal. ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009)). "'*Any possible effect,* whether

[2] The Secretaries of the Interior and Commerce are charged with implementing the ESA, and they have delegated their responsibilities to the Services. *See Turtle Island Restoration Network v. Nat'l Marine Fisheries Serv.*, 340 F.3d 969, 973-74 (9th Cir. 2003) (citing 50 C.F.R. § 402.01).

beneficial, benign, adverse or of an undetermined character,' triggers the requirement." *Id.* (quoting *Lockyer*, 575 F.3d at 1018-19). "[A]n agency may not duck its consultation requirement, whether based on limited resources, agency priorities or otherwise." *Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 188 n.10 (D.C. Cir. 2017). It may avoid consultation only if it determines that its proposed action will have "no effect" on listed species or critical habitat. *Karuk Tribe*, 681 F.3d at 1027.

STATEMENT OF THE CASE

I. Factual background

A. Antibiotic resistance poses a grave and growing threat to human health

The introduction of antibiotics in the 1940s "transformed modern medicine." CDC Antibiotic Report 18; *see id.* at 11-12. By killing or stopping the growth of microorganisms that cause bacterial infections, antibiotics enable medical professionals to treat both common and complex infections. CDC, *Antibiotic Use Questions and Answers*, https://www.cdc.gov/antibiotic-use/q-a.html (last reviewed Oct. 6, 2021); CDC Antibiotic Report viii. Antibiotics provide "one of our most powerful tools for fighting life-

threatening infections," CDC Antibiotic Report 3, and have saved millions of lives, *id*. at 18.

For nearly as long as we have relied on antibiotics to treat diseases, we have known that antibiotic use leads, inevitably, to antibiotic resistance. *See NRDC v. FDA*, 760 F.3d 151, 152-53 (2d Cir. 2014); *see also* 1-ER-40 ("Bacteria will inevitably find ways of resisting the antibiotics developed by humans . . . ."). More use leads to more resistance. "Through repeated exposure to antibiotics, some strains of bacteria develop resistance or immunity." *NRDC*, 760 F.3d at 153. These germs "develop the ability to defeat the antibiotics designed to kill them." CDC Antibiotic Report 2. They then "spread like wildfire," *id.* at 9, both by outcompeting germs without resistance traits and by sharing their resistance genes with germs that previously lacked such genes, *id.* at 5, 21. Resistance can quickly jump from one setting to another, including "communities, the food supply, healthcare facilities, [and] the environment (e.g., soil, water)." *Id.* Because bacteria that do not threaten human health can share resistance genes with bacteria that make people sick, even resistance that does not originate in

human pathogens can pose a risk to humans. *See* 1-ER-41; 2-ER-77, 231. Bacteria can, moreover, become "multidrug resistant" by developing and carrying mechanisms for resisting different antibiotics at the same time. CDC Antibiotic Report 7, 21. Multidrug resistance "can complicate clinical treatment when these bacteria incite human disease." 3-ER-289.

Antibiotic use is not, and never has been, limited to human medicine. Antibiotics are given to pets and used in animal agriculture to treat and prevent infections. CDC Antibiotic Report 18. Antibiotics are also sometimes applied to crops as pesticides to manage diseases. *Id*. All of these uses—whether "in people, animals, or crops"—can contribute to the development and spread of antibiotic resistance. *Id.* at 5.

The CDC considers antibiotic resistance "one of the greatest global public health challenges of our time." *Id.* at 3; *see also Antibiotic Resistance*, World Health Organization (WHO) (July 31, 2020), https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance (discussing scope of the challenge and recognizing that "[a]ntibiotic resistance is accelerated by the misuse and overuse of antibiotics").

Antibiotic-resistant infections "can be difficult, and sometimes impossible, to treat." CDC Antibiotic Report 5. In recent years, the challenge of antibiotic resistance has become "a global crisis." *Id.* at 8. "Without urgent action," antibiotic resistance threatens to make many modern medicines and treatments "obsolete." CDC, *Infographic: Antibiotic Resistance The Global Threat* (Dec. 30, 2019), https://www.cdc.gov/globalhealth/infographics/antibiotic-resistance/antibiotic_resistance_global_threat.htm. For instance, it endangers access to basic surgeries and procedures, "such as joint replacements, organ transplants, and cancer therapy," that carry increased infection risks. CDC Antibiotic Report 8.

These are not merely future risks: the "post-antibiotic era" is "already here." *Id.* at vi. "[W]e now live in an era when people . . . are dying from untreatable infections because of the emergence and spread of antibiotic resistance." *Id.* at 3. "More than 2.8 million antibiotic-resistant infections occur in the United States each year, and more than 35,000 people die as a result." *Id.* at vii. Even for those who survive, antibiotic resistance can

"require prolonged and/or costlier treatments, extend hospital stays, necessitate additional doctor visits and healthcare use, and result in greater disability." 1-ER-40.

B. EPA authorized use of a medically important antibiotic as a pesticide at an unprecedented scale

The antibiotic streptomycin has been deployed both in human medicine and agriculture, with streptomycin sulfate as the active ingredient. 1-ER-34. Streptomycin is a member of the aminoglycoside class of antibiotics. *Id.* The FDA classifies aminoglycosides as "highly important" to human medicine, *see* 3-ER-362, 364 [hereinafter "FDA Guidance #152"]; and the World Health Organization ranks them as "high priority critically important antimicrobials," WHO, Critically Important Antimicrobials for Human Medicine, 6th Revision 24 (2018). Healthcare providers rely on streptomycin to treat serious illnesses, including tuberculosis, plague, tularemia, and urinary tract infections. 1-ER-44; *see also* 2-ER-68 to -72 (discussing streptomycin's uses in human medicine). Streptomycin is often prescribed in combination with other antibiotics because the diseases it targets are becoming increasingly resistant to treatment. 1-ER-44; *see also*

CDC Antibiotic Report 4 (describing drug-resistant tuberculosis as a "serious threat" to human health).

EPA has authorized targeted uses of streptomycin as a pesticide on fruit and vegetable crops for decades. *See* 1-ER-42. These previous authorizations, while significant, were relatively small in scope, and focused on apple and pear orchards. *See* 3-ER-290. Unsurprisingly, many of the diseases that growers have treated with streptomycin have become resistant to it as a result. 1-ER-42. Nonetheless, beginning in 2016, EPA issued emergency authorizations for growers to use streptomycin on citrus crops in Florida, and later, in parts of California, in an effort to manage the impacts of citrus greening and citrus canker diseases. 1-ER-34.

On January 11, 2021, EPA issued an unconditional registration of streptomycin sulfate for use as a pesticide on citrus trees across the United States. *See* 1-ER-33. This was the largest approval ever of streptomycin for use in plant agriculture, 3-ER-292—indeed, the largest approval ever of *any* medically important antibiotic for use as a pesticide, 2-ER-223. EPA issued the registration in an attempt to manage citrus greening disease (also

known as Huanglongbing or HLB) and citrus canker disease—two diseases that have spread rapidly through Florida citrus groves and that threaten yields from citrus groves nationwide. *See* 1-ER-34; 1-ER-46 to -47; 3-ER-293 to -297.

The scale of antibiotic use contemplated by EPA's recent authorization is unprecedented. EPA projects that growers will spray citrus plants with approximately 650,000 additional pounds of streptomycin per year in Florida alone, 3-ER-290—a total of 18 times the annual amount previously used across all plant agriculture, *id*., and nearly 50 times the annual amount of *all* aminoglycosides prescribed in human medicine in the United States, 2-ER-223. Airblast sprayers will disperse pressurized droplets of streptomycin into the air, blanketing up to 764,000 acres of citrus trees nationwide. 1-ER-34, 43. The Registration will allow this sweeping use of streptomycin through January 2028. *See* 1-ER-48 (authorizing use for seven years).

C. In its haste to address citrus losses, EPA overlooked and underestimated serious public-health and environmental risks from streptomycin's use

There is no dispute that the citrus industry has suffered losses in recent years, and that citrus greening and citrus canker diseases contribute to the challenges growers face. 1-ER-46 (describing reduction in commercial citrus acres in Florida). But in registering streptomycin for use as a pesticide to combat these infections, EPA authorized a treatment that may prove worse than the disease, putting public health and the environment at risk of grave harm.

1. EPA failed to adequately analyze the significant public-health risk that the Registration will intensify antibiotic resistance

EPA acknowledged that spraying streptomycin on citrus orchards could contribute to antibiotic resistance in human pathogens. 1-ER-41. The Agency highlighted three routes of exposure by which resistance could spread: among the "general public, from residues on food"; among "agricultural workers through their daily activities"; and in "the environment, from treated orchards." 1-ER-42; *see also* 1-ER-41 ("For

antibiotic pesticides, resistance can be spread by resistant species in or on food, the skin of workers, or indirectly through the environment or clothing.").

Rather than develop a risk-assessment tool to analyze these particular risks, EPA coopted a tool used by another agency for another purpose—FDA Guidance #152. 1-ER-42. That risk assessment framework analyzes whether treating food-producing animals like pigs, cows, and chickens with antibiotics increases antibiotic resistance in food-borne bacteria. 3-ER-335. The tool's "primary focus" is "foodborne pathogens." *Id.* It "does not address" worker exposures, 1-ER-44, and does not account for the "much greater environmental exposure" to antibiotics that results when antibiotics are sprayed onto crops rather than administered to animals through medicated feeds or injections, 3-ER-290. Though EPA acknowledged both limitations, it did no supplemental analysis to address either exposure route.

Even without considering two of the three routes by which antibiotic resistance could spread from streptomycin's new uses as a pesticide on

citrus—through environmental pathways and farmworkers' daily activities—EPA concluded that the new uses posed a "medium" risk to human health. 1-ER-44.

2. EPA failed to sufficiently analyze risks to bees and other pollinators

EPA's risk assessment also pays short shrift to pollinators. Pollinators—including bees, birds, bats, butterflies, and more—"play a critical role in our food production system." Robert M. Nowierski, *Pollinators at a Crossroads*, U.S. Dep't of Agric. Blog (July 29, 2021), https://www.usda.gov/media/blog/2020/06/24/pollinators-crossroads. Honey bees, for example, "increase[] crop production and quality for a wide variety of foods, including fruits, nuts, vegetables, legumes," and others. *Id.* In total, "[p]ollination services add tens of billions of dollars to the value of agricultural crops annually." U.S. Dep't of Agric., 2021 USDA Annual Strategic Pollinator Priorities and Goals Report 3 (2021), https://www.usda.gov/sites/default/files/documents/pollinator-priorities-2021R4-508-version.pdf; *see also* FDA, *Helping Agriculture's Helpful Honey Bees*, https://www.fda.gov/animal-veterinary/animal-health-

literacy/helping-agricultures-helpful-honey-bees, (last updated July 30, 2018) ("About one-third of the food eaten by Americans comes from crops pollinated by honey bees, including apples, melons, cranberries, pumpkins, squash, broccoli, and almonds, to name just a few.").

Vital pollinator species "are at a critical crossroads." Nowierski, *Pollinators at a Crossroads*. In recent years, pollinator populations have experienced dramatic losses. *Id*. Pesticides are contributing to these declines. *Id*. As a result, EPA has issued several guidance documents for its risk assessors to use in "evaluating the potential risks of pesticides to bees" and other pollinators. EPA, Guidance on Exposure and Effects Testing for Assessing Risks to Bees 4-5 (2016) [hereinafter "EPA Pollinator Guidance"]; *see also* EPA, Process for Requiring Exposure and Effects Testing for Assessing Risks to Bees During Registration and Registration Review (2016) [hereinafter "EPA Pollinator Process Guidance"]; EPA, Health Can. Pest Mgmt. Regul. Agency & Cal. Dep't. of Pesticide Regul., Guidance for

Assessing Pesticide Risks to Bees (2014).[3] These guidance documents highlight that the minimum data routinely required by current regulations "may not always be sufficient" to "fully characterize the effects of a pesticide product" on pollinators. EPA Pollinator Process Guidance 7; *see also* 40 C.F.R. pt. 158 (setting forth general data requirements for pesticides); 40 C.F.R. § 158.1(b)(1) ("This part describes the minimum data and information EPA typically requires to support an application for pesticide registration . . . ."). Accordingly, the guidance documents "identify additional data that may be useful in evaluating effects of pesticides on honey bees." EPA Pollinator Guidance 7.

The applications to register streptomycin for use on citrus included only the single study assessing risks to pollinators generally required by EPA's regulations, and the Agency acknowledged that data about

[3] EPA Pollinator Guidance, https://www.epa.gov/sites/default/files/2016-07/documents/guidance-exposure-effects-testing-assessing-risks-bees.pdf; EPA Pollinator Process Guidance, https://www.epa.gov/sites/default/files/2016-08/documents/bee_guidance.pdf; EPA's Guidance for Assessing Pesticide Risks to Bees, https://www.epa.gov/sites/default/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf.

streptomycin's risks to pollinators were "incomplete." 1-ER-35; *compare* 40 C.F.R. § 158.630(d) (listing "guideline" test number 850.3020 on honey bee acute contact toxicity as generally required for any pesticide registration), *with* 3-ER-371 (reporting no acute-exposure effects from the single submitted "honey bee contact" study). The additional types of data set forth in EPA's Pollinator Process Guidance were "not available for streptomycin at this time." 1-ER-36; 3-ER-371. Despite being on notice that citrus flowers are "highly attractive" to bees, and although streptomycin will be applied while citrus flowers are in bloom, *see* 2-ER-230, EPA did not seek additional data, such as the chronic exposure data described in EPA's Pollinator Process Guidance, from the applicants; nor did it conclude that the single study before it adequately assessed risks to pollinators. Instead, the Agency stated that it was "currently determining whether additional pollinator data are needed for streptomycin" and issued its authorization without making that determination. 1-ER-36.

3. EPA did not assess risks to endangered species

EPA granted the Registration without first analyzing whether spraying streptomycin on citrus crops may affect any endangered or threatened species or their critical habitat. 2-ER-194; *accord* 1-ER-35. EPA conceded that this failure violated the ESA and moved for a remand to conduct the required ESA analysis. EPA Mot. for Remand, ECF No. 42-1 at 2, 11-13. Indeed, EPA admits it has *never* conducted a proper ESA analysis as part of its pesticide registration for *any* antibiotic. 2-ER-135.

D. EPA justified streptomycin's risks based on asserted benefits that lack adequate support

To determine whether the risks posed by streptomycin's new uses were "unreasonable," EPA also assessed the countervailing benefits. 3-ER-293 to -294. The Agency recognized that streptomycin would not cure either citrus greening or citrus canker disease, 3-ER-293, and presented no data on the antibiotic's potential for preventing infection when applied to healthy trees. Nonetheless, EPA concluded that streptomycin's use would likely provide benefit by mitigating both diseases to some degree. 3-ER-301.

With respect to citrus greening disease, EPA reviewed data from a single set of trials, conducted by one of the pesticide applicants, purporting to show that streptomycin is effective for treating the disease. *See* 3-ER-296 to -297. The Agency did not address independent, peer-reviewed research that reached the opposite conclusion. Petitioners highlighted this contrary research in their comments to the Agency, *see* 2-ER-237 & n.72 (discussing Zhang study, which found that "streptomycin is not effective at treating citrus greening disease"), but received no relevant response, *see* 2-ER-176 (responding only to other aspects of the study).

With respect to citrus canker disease, EPA likewise relied on a single set of trials conducted by the same applicant. 3-ER-300. Those trials compared signs of disease in infected trees treated with both streptomycin and copper against a control group of infected trees that were left untreated. *Id.* The trials did not evaluate trees treated with either streptomycin alone or copper alone. *Id*. Notably, copper-based pesticides are the "typical[]" means of treating citrus canker, 3-ER-298, and neither

the applicant nor EPA explained how any of the observed treatment benefits could be attributed to streptomycin, as opposed to copper.

In addition, though EPA registered streptomycin for use on citrus to both treat and prevent citrus greening and citrus canker diseases, 1-ER-5, the record includes no data on preventative use on uninfected trees. *See generally* 3-ER-295 to -301 (discussing only the purported benefits of using streptomycin to treat infected trees). EPA did not provide an explanation for extrapolating prevention benefits from data that evaluated only streptomycin's efficacy in treating infected trees.

II. Procedural Background

On March 25, 2021, Petitioners filed a petition for review asking this Court to set aside EPA's unconditional registration of streptomycin. *See* Pet. for Review, ECF No. 1-4. Petitioners asserted "that EPA violated the Endangered Species Act [ESA] by failing to consult with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service," *id.* at 1-2—a charge EPA now concedes, *see* EPA Mot. for Remand, ECF No. 42-1 at 2. Petitioners also asserted that EPA's action "violated the Federal Insecticide,

Fungicide, and Rodenticide Act [FIFRA] because the Agency failed to ensure that the use of streptomycin would not cause unreasonable harm to human health or the environment." *Id*. at 1 (citing 7 U.S.C. §§ 136a(c)(5)(C), (D), 136(bb)).

More than 10 months later, EPA moved for remand without vacatur based on its conceded violation of the ESA. *See generally* EPA Mot., ECF No. 42-1. In light of the seriousness of the Agency's error and the grave risks that the continued use of streptomycin poses to people and imperiled species, Petitioners cross-moved for remand with vacatur. Pet'rs' Opp'n to EPA's Mot. for Remand without Vacatur and Cross-Mot. to Vacate, ECF No. 45-1. The Court denied both motions without prejudice and set a schedule for merits briefing, Order 1-2, ECF No. 51, which was later extended, Order Approving Pet'rs' Streamlined Extension Req., ECF No. 52.

SUMMARY OF ARGUMENT

EPA violated FIFRA because the Agency lacked substantial evidence to conclude that its registration of streptomycin would not cause

"unreasonable adverse effects," 7 U.S.C. § 136a(c)(5)(C), (D), on human health or the environment, for three independent reasons.

First, EPA failed to assess adequately the risk that the Registration will intensify antibiotic resistance and thereby harm human health. Relying on an overly narrow risk assessment framework, EPA overlooked the risk that spraying streptomycin on citrus trees will cause antibiotic resistance to spread to human pathogens through environmental pathways like air, water, and soil. In addition, the Agency assumed that PPE requirements would sufficiently protect farmworkers and their communities from the risk of antibiotic-resistant infections—notwithstanding uncontroverted record evidence of substantial noncompliance with such requirements.

Second, EPA conducted a deficient evaluation of risks to pollinators. The Agency relied on a single study to analyze streptomycin's risk to pollinators and conceded that "the pollinator data are incomplete." 1-ER-35. Without either requiring additional studies or explaining why no additional studies were needed, EPA lacked substantial evidence to

conclude that streptomycin would not pose an unreasonable risk to pollinators and hence the environment.

Third, EPA accepted the applicants' claims of streptomycin's benefits despite the absence of substantial evidentiary support. The record is devoid of evidence that streptomycin is effective for treating citrus canker in infected trees, and the Agency completely overlooked evidence that streptomycin is ineffective for treating citrus greening. EPA also approved streptomycin's preventative use on uninfected trees despite not having any evidence that such use would be beneficial.

In addition, EPA violated the ESA—as the Agency concedes—by failing to make the required determination of whether the Registration "may affect" any endangered or threatened species or those species' critical habitats. 50 C.F.R. § 402.14(a).

Vacatur is the presumptive remedy for EPA's legal violations, and the Agency cannot overcome that presumption. EPA's violations of FIFRA and the ESA are each fundamental errors that merit vacatur. In addition, the Registration threatens to exacerbate the serious risk of antibiotic

resistance among human pathogens, and may imperil vulnerable mammals and pollinators. These risks far outweigh the speculative benefits that the Registration offers. Petitioners respectfully ask this Court to vacate and remand the Registration.

STANDARD OF REVIEW

A pesticide-registration order under FIFRA "shall be sustained" only "if it is supported by substantial evidence." 7 U.S.C. § 136n(b). "Substantial evidence means more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *NRDC v. EPA*, 857 F.3d 1030, 1036 (9th Cir. 2017) (quoting *NRDC v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013)). The agency's reasoning must be internally consistent. *See NRDC v. EPA*, 31 F.4th 1203, 1210 (9th Cir. 2022). Although this standard of review is "relatively deferential to the agency factfinder, [the Court's] review still must be 'searching and careful, subjecting the agency's decision to close judicial scrutiny.'" *Containerfreight Corp. v. United States*, 752 F.2d 419, 422 (9th Cir. 1985) (citation omitted).

Review under the substantial-evidence standard requires "greater scrutiny" by the Court than under the arbitrary-and-capricious standard of the Administrative Procedure Act. *Union Oil Co. of Cal. v. Fed. Power Comm'n*, 542 F.2d 1036, 1041 (9th Cir. 1976); *see also* 5 U.S.C. § 706(2) (providing that courts shall "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"). Consequently, "if the EPA's pesticide registration is arbitrary and capricious, EPA cannot show it was supported by substantial evidence." *Pollinator Stewardship Council*, 806 F.3d at 533 (Smith, N.R., J., concurring). Under either standard, an "agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). Agency action fails to meet these standards if an agency failed to consider adequate relevant data, *see Pollinator Stewardship*

Council, 806 F.3d at 532, or "entirely failed to consider an important aspect of the problem," *Motor Vehicle Mfrs. Ass'n of U.S.*, 463 U.S. at 43.

Review under the ESA is governed by the Administrative Procedure Act's arbitrary-and-capricious standard. *NRDC*, 2022 WL 2184936, at *7; *Nat'l Fam. Farm Coal.*, 966 F.3d at 923.

ARGUMENT

I. EPA's registration of streptomycin violates FIFRA

Antibiotic resistance threatens human lives and adds significant costs to an already-strained healthcare system. *See supra* Statement of the Case I.A; CDC Antibiotic Report 3; 1-ER-40. Consistent with the need for "aggressive action" to stem this public-health crisis, CDC Antibiotic Report 9, the CDC, FDA, and U.S. Department of Agriculture have all expressed "concerns on expanding uses of antibiotics in plant agriculture." 1-ER-50.

Despite these concerns, and despite the unprecedented scale of the proposed use of streptomycin—by far the largest use ever, of any antibiotic in plant agriculture, *see supra* Statement of the Case I.B.—EPA unduly limited the scope of its risk analyses, ignored material data gaps, and made

unfounded assumptions regarding streptomycin's risks and benefits. Specifically, EPA (1) performed a deficient evaluation of the risk the Registration poses to public health by increasing the spread of antibiotic resistance; (2) failed to adequately assess the risk the Registration poses to pollinators; and (3) unreasonably credited streptomycin with benefits that lack adequate support in the record. EPA conducted a flawed analysis under FIFRA, leaving the Agency with "no real idea" of how the Registration would harm the environment, *Pollinator Stewardship Council*, 806 F.3d at 532, or exacerbate the ongoing, urgent danger of antibiotic resistance. The Agency's decision to register streptomycin therefore lacks support by substantial evidence, is arbitrary and capricious, and violates FIFRA.

A. EPA did not adequately assess risks to human health from increased antibiotic resistance

Despite the serious human-health harms posed by increased antibiotic resistance, *see supra* Statement of the Case I.A, EPA failed to conduct a reasonable review of how the Registration may amplify or accelerate those risks. EPA's analysis of the threat to human health from

increased antibiotic resistance was flawed in two key ways. First, EPA relied on a risk-assessment framework that was designed to evaluate antibiotic use in a completely different context—animal agriculture—and thereby overlooked the risk that airblasting streptomycin onto large groves of citrus plants will intensify the spread of antibiotic resistance through environmental pathways like air, water, and soil. *See supra* Statement of the Case I.C.1. Second, EPA failed to accurately assess the heightened risk of exposure to streptomycin and streptomycin-resistant bacteria faced by farmworkers and their communities, instead assuming—despite contrary evidence—that PPE will provide adequate protection from harm. Both failures undermine EPA's conclusion that the Registration does not pose an unreasonable risk of harm to human health.

1. EPA failed to assess the risk that antibiotic resistance will spread through environmental pathways

EPA's reliance on an unduly narrow risk-assessment framework, designed by another agency to be used for another purpose, caused the Agency to overlook the potential spread of streptomycin resistance through environmental pathways. In its Final Registration Decision, EPA

focused on three ways in which antibiotic resistance could be spread: among the "general public, from residues on food"; among "agricultural workers through their daily activities"; and in "the environment, from treated orchards." 1-ER-42. Yet the Agency based its risk assessment on a tool that assesses only one of these exposure pathways: "the transmission of foodborne bacteria of human health concern *through the consumption of . . . food products*." 3-ER-335 (emphasis added).

As EPA acknowledged, the risk-assessment framework the Agency used—FDA Guidance #152—was designed to evaluate the risks of antibiotic use in animal husbandry. 3-ER-286. Because the FDA believes that consumption of animal food products constitutes "the most significant pathway for human exposure" to antibiotic-resistant bacteria in that context, the guidance focuses narrowly on risks arising from contact with foodborne bacteria. 3-ER-335. But according to EPA, treating food animals with antibiotics, which involves administering antibiotics "directly to animals in medicated feeds or by injection," causes "much less environmental exposure compared to agricultural sprays of antibiotics."

3-ER-290. FDA Guidance #152 is thus inappropriate for assessing the significant environmental exposures that result when antibiotics are sprayed as pesticides onto plants. *See* 3-ER-336 (describing the risk analysis method as a means for evaluating "the potential microbiological effects of antimicrobial new animal drugs *on food-borne* bacteria" (emphasis added)).

Despite recognizing the "dissimilarities" between the risks FDA Guidance #152 was designed to address and those posed by the Registration, 3-ER-286, EPA relied on the guidance as its sole tool for assessing the Registration's effects on antibiotic resistance. Among other things, the Agency hewed closely to FDA Guidance #152's exposure assessment, which considers the "probability for humans to ingest [the] bacteria in question from the relevant food commodity." 3-ER-338, fig.1. As a result, EPA's assessment focused on human exposure to streptomycin-resistant bacteria from eating treated citrus. *See* 3-ER-290 (asserting that "[t]he human health concern comes mostly from contamination of food crops with bacteria of human health concern and the selection or transfer of resistance traits to these microbes of human health concern"); 1-ER-43.

Although EPA purported to "adapt[]" FDA Guidance #152 "to plant agricultural use of antibiotics," 3-ER-286, the Agency did not supplement its analysis to account for the "much greater environmental exposure due to the application [of streptomycin] by air blast," 3-ER-290. Rather, EPA dismissed the risk of human exposure to streptomycin-resistant bacteria through environmental pathways by asserting—without support—that "human pathogens are a relatively minor component of the general agricultural environment." *Id.*

This statement conflicts with EPA's own concession that "there is little evidence for *or against* the presence of microbes of human health concern in the plant agricultural environment." 2-ER-182, 184 (emphasis added). And regardless of how prevalent human pathogens are in agricultural areas, it was unreasonable for EPA to dismiss the risk posed by antibiotic resistance spreading through environmental pathways. This is in part because streptomycin can easily move beyond treated fields, come into contact with human pathogens off-field, and cause resistance to develop among those off-field human pathogens.

Indeed, the record is replete with evidence—including from EPA itself—that human exposures to streptomycin can occur beyond the immediate agricultural areas where it is sprayed. For example, EPA recognized that "[h]umans may be exposed to streptomycin . . . in . . . drinking water, since streptomycin may be applied directly to growing crops and application may result in streptomycin reaching surface and ground water sources of drinking water." 3-ER-314. The Agency also observed that there is potential for "exposure in residential areas to streptomycin resulting from spray drift from agricultural applications." *Id.* The likelihood of such off-field exposures is substantially amplified by EPA's authorization of application of streptomycin via airblast, which is "the second most drift-prone dissemination method of a pesticide." 2-ER-234. Commenters also alerted EPA to potential human exposures to streptomycin through residues in soil and on the "boots, tools, work clothes, and skin of family members who handle pesticides or work in areas where they are applied and then return home." 2-ER-216. Although EPA considered whether human exposures to streptomycin through such

environmental pathways would have *toxicological* effects, *see* 3-ER-315 to -328, it failed to consider whether these same exposure pathways would increase people's risk of developing *antibiotic-resistant infections*.

This omission was particularly unreasonable insofar as EPA acknowledged that exposure to streptomycin creates "selection pressure" that facilitates the proliferation of streptomycin-resistant bacteria. *See* 3-ER-288, 289; *see also id.* (discussing study that "indicates that streptomycin resistance can appear in . . . bacteria on grapefruit leaves when streptomycin is employed to control citrus canker"); *see also* Statement of the Case I.A. (explaining how use of antibiotics leads to the development of antibiotic resistance within bacterial populations). Indeed, the Agency observed that bacteria will "inevitably" develop resistance to antibiotics. 1-ER-40. Yet EPA failed to assess the risk of human pathogens developing antibiotic resistance outside the agricultural environment through environmental pathways that will carry streptomycin off-field—including into neighboring communities.

Nor did EPA account for the fact that bacteria are highly mobile and can easily share resistance genes. Thus, plant bacteria that develop streptomycin resistance within citrus groves can routinely move off-field, come into contact with off-field human pathogens, and then transfer resistance to those off-field human pathogens. In their comments on the Proposed Registration, Petitioners reminded EPA that antibiotic-resistant bacteria can be spread through air, water, soil, and insect vectors. 2-ER-216, 226, 231 & n.18; *see* 2-ER-210 to -211. Petitioners also noted the "ease with which [antibiotic-resistance] traits can transfer from bacteria that are not of human health concern to those that are." 2-ER-231. EPA itself recognized that "the transfer of antibiotic resistance between bacterial species is well-documented," 2-ER-184, and that "human pathogens and plant pathogens may exist concurrently, allowing for the potential for resistance to develop in human pathogens as a result of antibiotic use on crops," 1-ER-41. In other words, even if most bacteria that acquire streptomycin resistance within citrus groves would not directly infect people, *see* 2-ER-184, those

bacteria could easily move off-field and transfer their resistance traits to human pathogens. EPA failed to account for this risk.

The Agency thus "entirely failed to consider," *Motor Vehicle Mfrs. Ass'n of U.S.*, 463 U.S. at 43, the risk that widespread streptomycin use will lead to increased antibiotic resistance among off-field human pathogens. Because it failed to evaluate the risk that the expanded use of streptomycin on citrus will facilitate the spread of antibiotic resistance to human pathogens through environmental pathways, EPA lacked substantial evidence to conclude that the Registration would not pose "unreasonable adverse effects" on human health. 7 U.S.C. § 136a(c)(5)(C), (D).

2. EPA failed to consider evidence that real-world PPE use will not adequately protect farmworkers from streptomycin-resistant bacteria

In addition to ignoring the risk that antibiotic resistance will spread through environmental pathways, EPA also failed to assess adequately the second of the "three routes of exposure" through which the Agency recognized "resistance can be spread": the daily activities of agricultural workers. 1-ER-41, 42. In its Final Registration Decision, EPA acknowledged

that its unconditional registration of streptomycin may expose farmworkers to antibiotic-resistant bacteria. *See* 1-ER-44. The Agency also recognized that FDA Guidance #152 does not account for that exposure. *See id.* Yet EPA dismissed this exposure route with a cursory reference to the Agency's "belie[f] that requiring additional Personal Protective Equipment (PPE) . . . will reduce the contribution of occupational exposure to the overall risk estimations." *Id.* EPA failed to support its belief that PPE requirements would adequately reduce the risk of occupational exposures to streptomycin or streptomycin-resistant bacteria and disregarded record evidence to the contrary. Furthermore, the Agency failed to consider the likelihood that PPE requirements would not protect farmworkers from acquiring streptomycin-resistant infections beyond occupational settings.

i. EPA ignored studies documenting substantial noncompliance with PPE requirements

Under FIFRA, EPA may register a pesticide only if it determines that the pesticide will not generally cause unreasonable adverse effects on the environment "when used in accordance with widespread and commonly recognized practice." 7 U.S.C. § 136a(c)(5)(D). In other words, EPA's risk

analysis must be based on how the pesticide will actually be used—and not how it would be used under a hypothetical, best-case scenario. Because EPA ignored record evidence of substantial noncompliance with PPE requirements, the Agency's "belie[f]" that those requirements would sufficiently protect farmworkers against streptomycin exposure, 1-ER-44, is unreasonable.

In comments on the proposed registration, Petitioners presented EPA with evidence from publicly available studies, published in peer-reviewed journals, documenting the reality that "pesticide handlers frequently do not use PPE, often for reasons beyond their control." 2-ER-216 & nn.64-66. For example, one study found that less than 15% of 220 randomly selected farmworkers complied with pesticide-related PPE requirements. 2-ER-216 & n.64. Another study found that over 40% of surveyed agricultural workers believed there was no need to wear PPE while applying pesticides. 2-ER-216 & n.65. A third study found that 44% of surveyed farmworkers did not wear chemical-resistant gloves, and 78% did not wear other protective gear, at least 75% of the time they were handling pesticides.

2-ER-216 & n.66. These studies provide compelling evidence that, among farmworkers handling pesticides, non-compliance with PPE requirements is a widespread and commonly acknowledged practice.

The record includes no evidence undermining that conclusion. Instead, in response, EPA asserted that pesticide handlers are "required" to follow PPE requirements on pesticide labels, that "[f]ailure to wear the PPE as required on the label would be a violation of FIFRA," and that "EPA risk assessments are only reflective of labeling requirements and do not address misuse." 2-ER-152. The Agency also noted that it "require[s]" employers to provide assistance and training to workers who handle pesticides that require use of a respirator—apparently suggesting that this requirement supports the Agency's assumption that farmworkers will consistently wear PPE when handling streptomycin. *See id.*; 1-ER-7, 21 (requiring respirator use).

EPA's responses lack merit. FIFRA commands EPA to evaluate the risks posed by a pesticide "when used in accordance with widespread and commonly recognized practice," 7 U.S.C. § 136a(c)(5)(D), meaning that the

Agency may not ignore actual, prevalent behavior surrounding pesticide use. Here, uncontroverted record evidence showed that, for a variety of reasons, farmworkers often do not wear PPE as they are instructed to do—notwithstanding the existence of PPE-related requirements. Because noncompliance with PPE requirements is "widespread and commonly recognized," *id.*, FIFRA required EPA to take that reality into consideration when assessing risks to farmworkers. EPA's refusal to do so renders its risk assessment unreasonable.

Ninth Circuit precedent confirms this conclusion. In *National Family Farm Coalition v. EPA*, 960 F.3d 1120 (9th Cir. 2020), this Court held that EPA's registration of a pesticide was unsupported by substantial evidence in part because the Agency ignored record evidence of "substantial non-compliance with the EPA-mandated label" for the pesticide. *See id.* at 1139, 1144. As the Court acknowledged, noncompliance with the label would risk damage to crops, and "EPA entirely failed to acknowledge this risk." *Id.* at 1139. Here, similarly, Petitioners presented the Agency with evidence of substantial noncompliance with EPA-mandated label requirements for

PPE use. EPA entirely ignored this reality, and thus failed to properly consider streptomycin's risk to farmworkers.

EPA briefly attempted to justify its refusal to consider evidence of widespread noncompliance with PPE requirements by insisting that "the supporting information" for the farmworker surveys "need[ed] to be provided so that they [could] be reviewed in detail and corrective actions as appropriate [could] be determined." 2-ER-152. But EPA provided no reasonable basis for dismissing published studies that were properly before the Agency simply because public commenters did not simultaneously submit the underlying raw data. *Cf. League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 699-700 (9th Cir. 2021) (holding that EPA had to consider "peer-reviewed" studies that were "available—even if the underlying data is not"). Nor did the Agency make its purported need for these data known until the day it announced its decision to register streptomycin. *Compare* 1-ER-33 (Final Registration Decision, dated Jan. 11, 2021), *with* 2-ER 140, 152 (Response to Comments, dated Jan. 11, 2021).

To the extent that EPA required more data to assess the evidence before it, it was EPA's duty to solicit such data. FIFRA's implementing regulations provide that "EPA will approve an application under the criteria of [§ 136a(c)(5)] only if . . . [t]he Agency has determined that no additional data are necessary to make the determinations required by [§ 136a(c)(5)]." 40 C.F.R. § 152.112(c). If EPA required additional information to determine whether noncompliance with PPE requirements was a "widespread and commonly recognized practice," 7 U.S.C. § 136a(c)(5)(D), FIFRA's regulations required EPA to solicit those data. *See* 40 C.F.R. § 158.75 (providing that "additional data requirements will be imposed" if the data before the Agency are "not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment"). EPA's belated claim that it needed underlying survey data is not "a satisfactory explanation," *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43, for its refusal to consider the evidence before it of substantial noncompliance with PPE requirements.

EPA's flat refusal to consider this evidence undermines the Agency's analysis of whether the Registration would have unreasonable adverse effects on farmworkers and their communities. As a result, the Registration was not supported by substantial evidence.

ii. Even perfect PPE compliance would not prevent many likely farmworker exposures to streptomycin and streptomycin-resistant bacteria

Even assuming—contrary to record evidence—full compliance with PPE requirements among farmworkers in citrus groves, those requirements do not adequately protect farmworkers and their communities from exposures to streptomycin and streptomycin-resistant bacteria. EPA's contrary conclusion is not supported by substantial evidence.

EPA requires use of PPE only by farmworkers who are applying or otherwise handling streptomycin. *See* 1-ER-7 to -8, 21 to -22. This requirement does not protect against any other type of exposure—for example, occupational exposures that occur when farmworkers reenter fields where streptomycin has been sprayed; or additional exposures that

occur when streptomycin drifts off-field to where farmworkers, their families, and surrounding communities live.

Although EPA generally prohibits worker reentry into treated fields within 12 hours of treatment, *see* 1-ER-10, 24, there is no evidence that this 12-hour interval adequately prevents exposure. On the contrary, the record indicates that it takes between 13 and 49 days for streptomycin residues in soil to decrease by half. *See* 3-ER-369. Thus, farmworkers and others who enter treated fields in the days and weeks after treatment are likely to be exposed to streptomycin residues but are not subject to any PPE requirements. EPA failed entirely to assess the risks of antibiotic-resistant infections associated with these exposures.

Compounding this problem, the Agency's 12-hour reentry prohibition appears to be aimed solely at reducing risks of toxicological effects from exposures to streptomycin, *see, e.g.*, 2-ER-155 (explaining that the Agency included the reentry restrictions "[i]n order to protect against [allergic] reactions"), rather than risks of acquiring streptomycin-resistant infections. These are distinct risks, and the Agency completely failed to

assess whether the reentry prohibition would sufficiently reduce the risk that farmworkers will acquire streptomycin-resistant infections through contact with either streptomycin residues or streptomycin-resistant bacteria that remain present in citrus groves more than 12 hours after the antibiotic has been sprayed.

Moreover, given that streptomycin is applied by airblast, it is likely to drift beyond the fields on which it is sprayed, where it will then exert selection pressure on off-field bacteria to develop resistance. *See supra* Argument I.A.1; *see*, *e.g.*, 3-ER-314 (acknowledging, in the context of assessing health risks from exposures to streptomycin itself, that there is potential for "exposure in residential areas to streptomycin resulting from spray drift from agricultural applications"); 2-ER-234 (describing airblast as "the second most drift-prone dissemination method of a pesticide"). Even perfect compliance with PPE requirements among those handling and spraying streptomycin will do nothing to protect farmworkers, their families, and surrounding communities from the increased risk of antibiotic-resistant infections resulting from spray drift.

EPA's failure to examine these risks undermines its assessment of the potential harms associated with widespread use of streptomycin in citrus production. Without considering the ways in which PPE requirements fail to address likely exposure scenarios, EPA lacked substantial evidence to conclude that farmworker exposures to streptomycin would not pose an unreasonable risk of antibiotic-resistant infections among workers and their communities.

B. EPA failed to conduct an adequate risk assessment for pollinators

EPA's failure to adequately consider the risks posed by the Registration extends beyond harms to public health: EPA also failed to properly assess the threat the Registration poses to pollinators.

Bees and other pollinator species are vital to the environment and our food system. They increase both the quantity and quality of food crops, adding billions of dollars to crop values each year. *See supra* Statement of the Case I.C.2. But they are highly susceptible to multiple stressors, including pesticides. *Id.*; EPA Pollinator Guidance 4-5. These stressors have

caused what this Court has described as the "precariousness of bee populations." *Pollinator Stewardship Council*, 806 F.3d at 532.

After observing steep declines in pollinator populations, the federal government has acknowledged the need to protect the health and survival of bees and other pollinators. *See* EPA Pollinator Guidance 6. Evaluating threats to pollinators is an important part of EPA's work in determining whether registering a pesticide would cause unreasonable adverse effects on the environment. *See id.* at 7-8; 7 U.S.C. § 136a(c)(5)(C), (D).

To register a pesticide, EPA must have "sufficient data to evaluate the environmental risks," *Pollinator Stewardship Council*, 806 F.3d at 523, and must determine, based on those data, that the pesticide will not cause unreasonable adverse effects. EPA may issue a registration only if "the Agency has determined that no additional data are necessary" to determine whether use of the pesticide will cause unreasonable adverse effects. 40 C.F.R. § 152.112(c) (citing 7 U.S.C. § 136a(C)(5)). If EPA determines that an applicant's data are "not sufficient to evaluate the

potential of the product to cause adverse effects," then "additional data requirements *will* be imposed." *Id.* § 158.75 (emphasis added).

Here, EPA stated outright that "the pollinator data are incomplete." 1-ER-35. While the applicants submitted the single study on acute toxicity to adult honey bees that EPA's regulations typically require for every pesticide application, *see supra* Statement of the Case I.C.2, EPA described the study as providing "limited" data, 3-ER-376. EPA acknowledged that "additional studies"—for instance, studies examining effects on larva and effects from chronic exposure—"are not available for streptomycin at this time." 1-ER-36. The Agency indicated that it was "currently determining" whether it needed to gather such data. *Id.*

EPA's decision to issue the Registration without "determin[ing] that no additional data are necessary," 40 C.F.R. § 152.112(c), violated FIFRA and EPA's own regulations. FIFRA requires EPA to determine whether the available data are complete before, not after, unconditionally approving new uses of a pesticide. *See Pollinator Stewardship Council*, 806 F.3d at 523. Neither the statute nor EPA's implementing regulations allow the Agency

to give the greenlight to a pesticide unless EPA affirmatively concludes, based on data that it deems sufficient, that a pesticide will have no unreasonable adverse effects. Indeed, this Court held that EPA's registration of the pesticide sulfoxaflor was not supported by substantial evidence "in the absence of sufficient data documenting the risk to bees." *Id.* at 532. "Without sufficient data," the Court explained, "EPA has no real idea whether sulfoxaflor will cause unreasonable adverse effects on bees, as prohibited by FIFRA." *Id.*; *see also NRDC v. EPA*, 2022 WL 2184936, at *8-9 (explaining that EPA's conclusion that the pesticide glyphosate is not likely to cause cancer was inconsistent with the Agency's acknowledgment that it could not, based on the available evidence, determine the association between exposure to glyphosate and the risk of developing non-Hodgkin's lymphoma).

EPA's regulations clearly govern what should happen if the Agency cannot reach the conclusion that a pesticide will not have unreasonable adverse effects based on the data before it: "additional data requirements *will* be imposed" on the applicant. 40 C.F.R. § 158.75 (emphasis added).

That is not what happened here. Instead, despite conceding that it had only "limited," 3-ER-376, and "incomplete," 1-ER-35, data about the pesticide's effects on pollinators, EPA issued the Registration. Because the Agency lacked substantial evidence to conclude that streptomycin would not have unreasonable adverse effects on pollinators, its decision was unlawful.

EPA's issuance of the Registration was also unreasonable for a second reason: the Agency invoked its own guidance for conducting FIFRA risk assessments for pollinators, but then departed, without any explanation, from that guidance. In the past decade, EPA has issued multiple guidance documents outlining how its risk assessors should evaluate the potential effects of pesticides on pollinators. *See* EPA Pollinator Guidance; EPA Pollinator Process Guidance; EPA et al., Guidance for Assessing Pesticide Risks to Bees (June 19, 2014). While not binding, these guidance documents identify additional studies—beyond the single acute-toxicity study generally required for all pesticide applications—that "EPA has determined are necessary to more fully evaluate the potential exposure and effects to bees for various pesticide use

patterns." EPA Pollinator Process Guidance 5. Here, EPA cited its 2016 Pollinator Process Guidance in its Final Registration Decision, recognizing that streptomycin's use patterns on citrus may require the additional studies described in the guidance to fully assess risks to pollinators. *See* 1-ER-36 (linking to EPA Pollinator Process Guidance). The Agency acknowledged that such studies "are not available for streptomycin at this time." *Id.* Yet EPA neither required the applicants to submit such studies, nor explained why it was choosing not to follow its own guidance here.

"Inconsistent reasoning"—including "invocation" of guidelines that an agency "fails to abide by"—is, "absent explanation, 'the hallmark of arbitrary action.'" *NRDC v. EPA*, 2022 WL 2184936, at *13 (citation omitted); *see also NRDC v. EPA*, 31 F.4th 1203, 1210 (9th Cir. 2022) (holding that EPA's decision was not supported by substantial evidence where the Agency, among other things, "abandon[ed] its own guidance . . . without a discernable rationale"). While EPA was not bound to follow its own guidance, it at least needed to provide *some* explanation for why, after specifically acknowledging that certain studies may be needed but were

not available, it could reasonably conclude that streptomycin will not have unreasonable adverse effects on pollinators. The Agency entirely failed to provide an explanation.

This failure is particularly troubling because the record suggests that the additional studies set forth in EPA's Pollinator Process Guidance *would* have provided the Agency with a fuller understanding of streptomycin's risks to pollinators, and may well have impacted EPA's assessment of streptomycin's adverse effects. Citrus flowers "are renowned magnets for bees," and bloom at times of year when streptomycin treatments will occur. 2-ER-230. If the Agency had required applicants to submit the additional studies called for in its Pollinator Process Guidance, those studies would have provided data on the potential impacts of chronic exposure to streptomycin on both adult and larval honey bees. *See* 1-ER-36. Such studies are particularly relevant here, where streptomycin's seven-year Registration means that pollinators will undergo repeated exposures to the antibiotic throughout their life cycles. When Petitioners urged EPA to require and review additional studies before approving an

unprecedentedly large use of streptomycin, 2-ER-230, the Agency agreed that "[w]e have no specific chronic toxicity data on honey bees" for streptomycin, 2-ER-194. EPA nonetheless dismissed Petitioners' concerns, suggesting, without any evidentiary support, that data about bee exposures to other antibiotics, in other contexts, somehow answered the question of whether chronic exposure to streptomycin would harm bees. 2-ER-194 to -195.

By its own admission, EPA lacked sufficient data to evaluate whether the Registration posed a risk to already-stressed pollinator species, and, as a result, to the environment. *See* 7 U.S.C. § 136a(c)(5)(C), (D); *Pollinator Stewardship Council*, 806 F.3d at 523. And EPA failed to provide *any* reason for disregarding its own guidance, despite acknowledging that the guidance sets forth studies that may be necessary to fully assess streptomycin's effects on bees and other pollinators. For both reasons, the Agency's decision to issue the Registration was unlawful and not supported by substantial evidence.

C. The purported benefits of streptomycin's use as a pesticide are not supported by substantial record evidence

EPA's determination that the Registration would not cause "unreasonable adverse effects," 7 U.S.C. § 136a(c)(5)(C), (D), was flawed not only because of the Agency's inadequate analyses of streptomycin's risks to public health and pollinators, but also because EPA failed to conduct an adequate assessment of streptomycin's supposed benefits. EPA's benefits analysis was unreasonable for three reasons.

First, EPA failed to identify *any* evidence that supports its conclusion that streptomycin is an effective treatment for citrus canker disease. When registering a pesticide, EPA "cannot rely on ambiguous studies as evidence of a conclusion that the studies do not support." *Pollinator Stewardship Council*, 806 F.3d at 531. Yet here, EPA did precisely that. To demonstrate streptomycin's purported efficacy for treating citrus canker disease, the applicant submitted only a single study of trials that showed that streptomycin and copper, *when used together*, can mitigate the effects of that disease. *See* 3-ER-300 (explaining trials using "streptomycin + copper"). But copper is a known effective treatment for citrus canker. *See* 3-ER-298. Thus,

in the absence of a control group showing the treatment effects of copper alone, or streptomycin alone, *see* 3-ER-300, it is impossible to determine which, *if any*, of the benefits observed in the study can be attributed to streptomycin. The ambiguous results from that study provide a flawed foundation for EPA's conclusion that streptomycin is an effective treatment for citrus canker disease. *See Pollinator Stewardship Council*, 806 F.3d at 531.

Second, EPA ignored scientific evidence in the record that streptomycin is ineffective as a treatment for citrus greening disease. Petitioners presented EPA with "published research indicating that streptomycin is not effective at treating citrus greening disease." 2-ER-237 & n.72; *see* 2-ER-250 to -260 (Zhang study). Specifically, Petitioners cited a study that concluded that streptomycin (referred to in the study as "STR," 2-ER-252), was "not effective in eliminating or suppressing" citrus greening bacteria. 2-ER-255 to -256; *see also* 2-ER-257 (categorizing streptomycin as "non-effective"); 2-ER-258 (explaining results "indicat[ing] that six out of nine aminoglycoside antibiotics," including streptomycin, "were not effective in suppressing" citrus greening bacteria).

Rather than address this contrary finding, EPA simply dismissed the study by explaining that the study's evaluation of *other* antibiotics as treatments for citrus greening disease was not relevant. *See* 2-ER-176. Where "EPA nowhere acknowledge[s] the evidence in the record" contrary to its conclusions, it violates FIFRA. *See Nat'l Fam. Farm Coal.*, 960 F.3d at 1142. Here, EPA failed to acknowledge contrary evidence that undermined one of the core purported benefits on which the Agency relied to justify the Registration. This violated FIFRA. *See id*. at 1136, 1139-44; *see also Ctr. for Biological Diversity v. Zinke*, 900 F.3d 1053, 1068-69 (9th Cir. 2018) (holding that an agency "acted in an arbitrary and capricious manner" when it selectively relied on one study and failed to consider contrary evidence from a different study).

Third, for both citrus greening and citrus canker, the applicant submitted studies only of streptomycin's effects on infected trees for *treatment*. *See* 3-ER-294 (citrus greening); 3-ER-300 (citrus canker). Yet EPA registered the pesticide for "use[] to treat *or prevent* infection." 1-ER-50; *see* 1-ER-8 to -10 (emphasis added). That broad approval allows growers to

apply the antibiotic to uninfected trees as a prophylactic measure, despite a lack of any evidence or discussion of the efficacy of this use. This would be akin to prescribing routine antibiotic treatments to a healthy person for the purpose of warding off potential future bacterial infections. EPA has cited no evidence that such use would be effective *at all*, much less any evidence that such use would be sufficiently beneficial to justify the potentially significant risks of intensifying antibacterial resistance to streptomycin. *See also* 2-ER-173 (failing to respond to Petitioners' comment that preventative use of streptomycin is ineffective and unwarranted).

For these reasons, EPA lacked substantial evidence to support streptomycin's purported benefits for addressing citrus greening and citrus canker disease. Where EPA reaches a conclusion "without evidence in the record to support the assumptions," a court "cannot find that the EPA's . . . finding is supported by substantial evidence as required by FIFRA." *NRDC v. EPA*, 857 F.3d at 1040. Here, the Agency did not have the necessary information to determine whether streptomycin's risks were

"unreasonable" in light of countervailing benefits, and EPA thus issued the Registration in violation of FIFRA's standard, 7 U.S.C. § 136a(c)(5)(C), (D).

II. As EPA concedes, the Registration violated the ESA

EPA conceded that it registered streptomycin without complying with the ESA's legal requirements. ECF No. 42-1 at 2; *accord* 1-ER-35; 2-ER-194. The Agency failed to comply with section 7 of the ESA, 16 U.S.C. § 1536, which "requires federal agencies to ensure that none of their activities" will "jeopardize" endangered or threatened species or "adversely modify" those species' critical habitat. *Karuk Tribe*, 681 F.3d at 1020; *see* 16 U.S.C. § 1536(a)(2). To meet this obligation, EPA must first "review its actions at the earliest possible time to determine whether any action *may affect* listed species or critical habitat." 50 C.F.R. § 402.14(a) (emphasis added). EPA failed to undertake even this initial step of the required ESA section 7 consultation process before registering streptomycin, and the Agency has conceded that legal violation to the Court. *See* ECF No. 42-1 at 2.

III. The Court should vacate streptomycin's registration

Given EPA's violations of FIFRA and the ESA, the Court should vacate and remand the Registration. Remand with vacatur is the presumptive remedy for unlawful agency action. *See NRDC v. EPA*, 2022 WL 2184936, at *13; *Alsea Valley All. v. Dep't of Com.*, 358 F.3d 1181, 1185 (9th Cir. 2004). This Court grants remand without vacatur "only in 'limited circumstances,'" and "only 'when equity demands.'" *Pollinator Stewardship Council*, 806 F.3d at 532 (first quoting *Cal. Cmties. Against Toxics v. EPA*, 688 F.3d 989, 994 (9th Cir. 2012); and then quoting *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995)).

This is not the rare case where the Court should depart from its usual practice of vacatur. In evaluating whether to remand without vacatur, the Court considers at least three factors: (1) "the seriousness of the agency's errors" weighed "against the disruptive consequences" of vacatur; (2) "the extent to which either vacating or leaving the decision in place would risk environmental harm"; and (3) whether an agency "would likely be able to offer better reasoning" for the same decision on remand or whether there

are "fundamental flaws" in the decision. *NRDC v. EPA*, 2022 WL 2184936, at *13 (citations omitted). Here, all three factors weigh heavily in favor of vacatur.

A. EPA's violations are serious legal errors that outweigh any disruptive consequences of vacatur

EPA's violations of FIFRA and the ESA are serious legal errors that outweigh any disruptive consequences. *See supra* Argument I, II; *Pollinator Stewardship Council*, 806 F.3d at 532.

EPA registered streptomycin without the necessary information to determine if the approval would cause "unreasonable adverse effects" on human health or the environment, 7 U.S.C. §§ 136a(c)(5)(C), (D), 136(bb). That oversight violates the fundamental core of FIFRA. "FIFRA's objective is to protect human health and prevent environmental harm from pesticides through a cost-benefit analysis of the pesticides." *Wash. Toxics Coal.*, 413 F.3d at 1032. FIFRA's registration standards are "safeguards put in place by Congress to ensure that approved pesticides do not cause adverse effects on the environment." *Nat'l Fam. Farm Coal.*, 966 F.3d at 909 (citing 7 U.S.C. § 136a). Consistent with FIFRA's overarching purpose and

the importance of its registration standards for effectuating that purpose, the Court has vacated registrations where "EPA substantially understated the risks it acknowledged" and "entirely failed to acknowledge other risks," *Nat'l Fam. Farm Coal.*, 960 F.3d at 1145—including in ways remarkably similar to those at issue here. For instance, in *National Family Farm Coalition*, the Court vacated a pesticide registration upon finding that EPA ignored evidence of noncompliance with label requirements and "substantially understated" the risk that the pesticide will drift off-field and damage non-target crops. *Id.* at 1144-45.

Here, EPA made multiple errors under FIFRA in granting the Registration. Notwithstanding the ongoing crisis of antibiotic resistance, EPA ignored the risk that resistance to streptomycin will spread to human pathogens through environmental pathways. The Agency also discounted the risk that farmworkers and their families will be exposed to streptomycin-resistant bacteria, by relying on PPE requirements despite uncontroverted evidence of substantial noncompliance with such requirements, and although those requirements do not even apply to many

exposures. In addition, EPA failed to require sufficient data on impacts to pollinators—despite the importance of these species and their susceptibility to harm from pesticides. *See supra* Statement of the Case I.C.2; 2-ER-229 to -226 & nn.33-38. On the other side of the analysis, EPA relied on purported benefits that lack substantial support in the record. Because EPA's errors go to the core of FIFRA's required registration analysis and undermine the statute's fundamental objective of safeguarding human health and the environment, they are serious and weigh in favor of vacatur.

EPA's admitted ESA violation is also serious, and independently weighs in favor of vacating streptomycin's registration. *See* Order 1-2, *Farmworker Ass'n of Fla. v. EPA*, No. 21-1079 (D.C. Cir. June 7, 2021) (per curiam) (vacating a pesticide registration partly based on "the seriousness" of EPA's conceded legal violation, where EPA—as here—failed to make an effects determination under the ESA). That is particularly so because EPA's violation is part of a longstanding pattern of noncompliance, rather than an isolated, anomalous error. "Even though EPA has approved over 1,000 pesticide ingredients and thousands of pesticide uses over the past

decades, it has met its ESA obligations for *less than 5 percent of those actions*." EPA, Balancing Wildlife Protection and Responsible Pesticide Use: How EPA's Pesticide Program Will Meet Its Endangered Species Act Obligations 9 (2022) [hereinafter EPA, Balancing Wildlife Protection and Responsible Pesticide Use], https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use_final.pdf (emphasis added).

EPA bears the burden to demonstrate that any "disruptive consequences" of vacatur outweigh these serious legal errors, and it cannot meet that burden here. *Pollinator Stewardship Council*, 806 F.3d at 532; *see All. for the Wild Rockies v. U.S. Forest Serv.*, 907 F.3d 1105, 1121-22 (9th Cir. 2018). Petitioners acknowledge the challenges that citrus greening and citrus canker diseases pose for agricultural growers. But, as was true in *National Family Farm Coalition*, the potential for some "adverse impact[s] on growers," 960 F.3d at 1145, does not overcome the risks associated with leaving the Registration in place. *See id.*; *cf. Cal. Cmties.*, 688 F.3d at 993-94 (denying vacatur where it would cause both serious environmental harm

and "economically disastrous" consequences to the power supply). That is particularly true here, where there is little evidence that leaving the Registration in place would resolve, or even significantly reduce, the targeted challenges. *See supra* Argument I.C.

EPA's legal errors are serious under both FIFRA and the ESA, and moreover extend a long pattern of ESA noncompliance. These critical errors outweigh the limited and speculative disruptive consequences of vacatur.

B. Leaving the Registration in place would risk significant harms to human health and the environment

The Registration—which authorizes the largest use ever of a medically important antibiotic in plant agriculture—threatens to exacerbate the already dire danger of antibiotic resistance, and to harm pollinators and threatened and endangered species during an extended remand period. Given these impacts, "leaving the EPA's registration . . . in place risks more potential environmental harm than vacating it." *Pollinator Stewardship Council*, 806 F.3d at 532; *see also* 7 U.S.C. § 136(bb) (defining "unreasonable

adverse effects on the environment" to include "any unreasonable risk to man or the environment").

Health risks stemming from the continued use of streptomycin on citrus are both real and immediate. Antibiotic resistance is a major public-health threat responsible for tens of thousands of U.S. deaths each year. *See* 2-ER-61 to -62. The use of streptomycin creates immediate pressure for antibiotic resistance to develop. 2-ER-79 to -81; *see also* CDC, *Antibiotic Resistance Questions and Answers*, https://www.cdc.gov/antibiotic-use/antibiotic-resistance.html (last reviewed Aug. 23, 2021) ("*Anytime* antibiotics are used, they can contribute to antibiotic resistance." (emphasis added)). Antibiotic use in the agricultural sector can broadly affect human health and communities, 2-ER-81 to -82, including by complicating treatment of human pathogens, 2-ER-82 to -83. That risk is particularly pronounced for farmworkers in citrus groves. 2-ER-73 to -75. EPA has acknowledged that antibiotic resistance causes human health risks, including disability and death, and significant healthcare costs. 1-ER-39 to -40.

Leaving the Registration in place while EPA attempts to comply with the ESA's requirements would also pose a threat to federally protected species. The Court weighs potential harms to endangered species particularly heavily when evaluating environmental harms, given Congress's clear direction "that under the ESA, the balance of hardships always tips sharply in favor of the endangered or threatened species." *Wash. Toxics*, 413 F.3d at 1035. Here, the Agency has estimated that it will take, at minimum, until Fall 2026 before it can complete an ESA effects determination for streptomycin. 2-ER-138. EPA's limited FIFRA analysis indicates that, in the meantime, streptomycin causes "potential risk to mammals from chronic exposure." 1-ER-35; *see also* 1-ER-49. The habitats and ranges of several endangered and threatened species, such as the Florida panther, the Florida bonneted bat, and the San Joaquin kit fox, overlap with zones of citrus agriculture. *See* 2-ER-91 to -121. These endangered and threatened mammal species face potential, ongoing risks from streptomycin's continued use on citrus.

Between the risks to people, pollinators, and imperiled species from streptomycin's continued use, leaving the Registration in place risks environmental harm, whereas vacating it would not. *See Pollinator Stewardship*, 806 F.3d at 532; *NRDC v. EPA*, 2022 WL 2184936, at *13.

C. EPA's errors are fundamental flaws requiring new analysis

The "'fundamental flaws' in EPA's analysis are so substantial that it is exceedingly 'unlikely that the same rule would be adopted on remand.'" *Nat'l Fam. Farm Coal.*, 960 F.3d at 1145 (quoting *Pollinator Stewardship Council*, 806 F.3d at 532).

EPA lacks the data it needs to support the Registration with new and better reasoning that would allow the Agency to make the findings that FIFRA requires. The Agency will have to take additional steps to demonstrate whether streptomycin performs its intended function without any "unreasonable adverse effects" on human health or the environment. 7 U.S.C. § 136a(c)(5)(C), (D). These steps include, for example, analyzing multiple environmental pathways for the spread of antibiotic resistance; evaluating real-world PPE use; potentially requiring new tests on the risk

to pollinators; obtaining a study on streptomycin's efficacy against citrus canker disease with a proper control group; and acquiring data on whether streptomycin is effective for preventing either citrus greening or citrus canker diseases when used prophylactically on uninfected trees. As a result, the Registration suffers from "fundamental flaws" under FIFRA.

For the ESA, EPA has acknowledged that it will take many years to remedy its violation. The Agency estimates that it will take at least until Fall 2026 to complete the initial step of ESA compliance. 2-ER-138. During that time, EPA "may encounter new or unexpected challenges in conducting its analyses and making effects determinations." *Id.* The Agency faces these difficulties, in large part, because it has never conducted an effects determination for *any* antibiotic used as a pesticide. 2-ER-135. Currently, "EPA does not have ESA methods specific to antimicrobials." EPA, Balancing Wildlife Protection and Responsible Pesticide Use 42. The Agency's existing risk assessment methods, which were designed for conventional pesticides, "do not apply to assessing antimicrobial uses." *Id.* at 35. Until EPA develops methods for

antimicrobials, which may take three years, *see id.* at 52, the Agency lacks even a framework to remedy the Registration's ESA violation. For this violation, "EPA has admitted that it will not provide the timely reconsideration that is the central rationale for remand without vacatur." Order 1, *Farmworker Ass'n of Fla. v. EPA*, No. 21-1079.

In sum, not only is vacatur the default remedy, but all three factors discussed above also tip strongly in favor of vacatur while no factor weighs against it. The Court should adhere to its ordinary practice and vacate streptomycin's registration.

CONCLUSION

For the reasons set forth above, Petitioners respectfully ask this Court to vacate EPA's registration of streptomycin for use as a pesticide on citrus, and remand the decision to the Agency with instructions to undertake the analyses required by both FIFRA and the ESA.

Dated: July 15, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of 9th Cir. R. 32-1(a) because it contains 12,939 words, excluding the parts of the brief exempted by 9th Cir. R. 32-1(c) and Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using 14-point Palatino Linotype font.

Dated: July 15, 2022

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ADDENDUM OF STATUTES AND REGULATIONS

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United States Code Annotated
Title 5. Government Organization and Employees (Refs & Annos)
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5 U.S.C.A. § 706

§ 706. Scope of review

Currentness

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

Notes of Decisions (5230)

5 U.S.C.A. § 706, 5 USCA § 706
Current through P.L. 117-159. Some statute sections may be more current, see credits for details.

End of Document

7 U.S.C.A. § 136

§ 136. Definitions

Effective: August 3, 1996
Currentness

For purposes of this subchapter--

(a) Active ingredient

The term "active ingredient" means--

(1) in the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest;

(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;

(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue; and

(5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria.

(b) Administrator

The term "Administrator" means the Administrator of the Environmental Protection Agency.

(c) Adulterated

The term "adulterated" applies to any pesticide if--

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

(d) Animal

The term "animal" means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish.

(e) Certified applicator, etc.

(1) Certified applicator

The term "certified applicator" means any individual who is certified under section 136i of this title as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or uses dilutions of registered pesticides consistent with subsection (ee), only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this subchapter.

(2) Private applicator

The term "private applicator" means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by the applicator or the applicator's employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

(3) Commercial applicator

The term "commercial applicator" means an applicator (whether or not the applicator is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

(4) Under the direct supervision of a certified applicator

Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

(f) Defoliant

The term "defoliant" means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

(g) Desiccant

The term "desiccant" means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

(h) Device

The term "device" means any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

(i) District court

The term "district court" means a United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

(j) Environment

The term "environment" includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.

(k) Fungus

The term "fungus" means any non-chlorophyll-bearing thallophyte (that is, any non-chlorophyll-bearing plant of a lower order than mosses and liverworts), as for example, rust, smut, mildew, mold, yeast, and bacteria, except those on or in living man or other animals and those on or in processed food, beverages, or pharmaceuticals.

(l) Imminent hazard

The term "imminent hazard" means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act of 1973.

(m) Inert ingredient

The term "inert ingredient" means an ingredient which is not active.

(n) Ingredient statement

The term "ingredient statement" means a statement which contains--

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

(o) Insect

The term "insect" means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

(p) Label and labeling

(1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter--

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if--

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: “Not Registered for Use in the United States of America”.

(2) A pesticide is misbranded if--

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if--

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing--

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter--

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

(r) Nematode

The term "nematode" means invertebrate animals of the phylum nemathelminthes and class nematoda, that is, unsegmented round worms with elongated, fusiform, or saclike bodies covered with cuticle, and inhabiting soil, water, plants, or plant parts; may also be called nemas or eelworms.

(s) Person

The term "person" means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

(t) Pest

The term "pest" means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 136w(c)(1) of this title.

(u) Pesticide

The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 321(w) of Title 21, that has been determined by the Secretary of Health and Human Services not to be

a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 321(x) of Title 21 bearing or containing a new animal drug. The term "pesticide" does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of Title 21. For purposes of the preceding sentence, the term "critical device" includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term "semi-critical device" includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

(v) Plant regulator

The term "plant regulator" means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term "plant regulator" shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

(w) Producer and produce

The term "producer" means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide. The term "produce" means to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide. The dilution by individuals of formulated pesticides for their own use and according to the directions on registered labels shall not of itself result in such individuals being included in the definition of "producer" for the purposes of this subchapter.

(x) Protect health and the environment

The terms "protect health and the environment" and "protection of health and the environment" mean protection against any unreasonable adverse effects on the environment.

(y) Registrant

The term "registrant" means a person who has registered any pesticide pursuant to the provisions of this subchapter.

(z) Registration

The term "registration" includes reregistration.

(aa) State

The term "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa.

(bb) Unreasonable adverse effects on the environment

The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

(cc) Weed

The term "weed" means any plant which grows where not wanted.

(dd) Establishment

The term "establishment" means any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.

(ee) To use any registered pesticide in a manner inconsistent with its labeling

The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling, except that the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling, (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, (5) any use of a pesticide in conformance with section 136c, 136p, or 136v of this title, or (6) any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this subchapter. After March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) Outstanding data requirement

(1) In general

The term "outstanding data requirement" means a requirement for any study, information, or data that is necessary to make a determination under section 136a(c)(5) of this title and which study, information, or data--

(A) has not been submitted to the Administrator; or

(B) if submitted to the Administrator, the Administrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under section 136a(c)(5) of this title and the regulations and guidelines issued under such section.

(2) Factors

In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

(gg) To distribute or sell

The term "to distribute or sell" means 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. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

(hh) Nitrogen stabilizer

The term "nitrogen stabilizer" means any substance or mixture of substances intended for preventing or hindering the process of nitrification, denitrification, ammonia volatilization, or urease production through action upon soil bacteria. Such term shall not include--

(1) dicyandiamide;

(2) ammonium thiosulfate; or

(3) any substance or mixture of substances. [1] --

(A) that was not registered pursuant to section 136a of this title prior to January 1, 1992; and

(B) that was in commercial agronomic use prior to January 1, 1992, with respect to which after January 1, 1992, the distributor or seller of the substance or mixture has made no specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatilization [2] urease production regardless of the actual use or purpose for, or future use or purpose for, the substance or mixture.

Statements made in materials required to be submitted to any State legislative or regulatory authority, or required by such authority to be included in the labeling or other literature accompanying any such substance or mixture shall not be deemed a specific claim within the meaning of this subsection.

(jj)[3] **Maintenance applicator**

The term "maintenance applicator" means any individual who, in the principal course of such individual's employment, uses, or supervises the use of, a pesticide not classified for restricted use (other than a ready to use consumer products pesticide); for the purpose of providing structural pest control or lawn pest control including janitors, general maintenance personnel, sanitation personnel, and grounds maintenance personnel. The term "maintenance applicator" does not include private applicators as defined in subsection (e)(2); individuals who use antimicrobial pesticides, sanitizers or disinfectants; individuals employed by Federal, State, and local governments or any political subdivisions thereof, or individuals who use pesticides not classified for restricted use in or around their homes, boats, sod farms, nurseries, greenhouses, or other noncommercial property.

(kk) Service technician

The term "service technician" means any individual who uses or supervises the use of pesticides (other than a ready to use consumer products pesticide) for the purpose of providing structural pest control or lawn pest control on the property of another for a fee. The term "service technician" does not include individuals who use antimicrobial pesticides, sanitizers or disinfectants; or who otherwise apply ready to use consumer products pesticides.

(ll) Minor use

The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where--

(1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or

(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and--

(A) there are insufficient efficacious alternative registered pesticides available for the use;

(B) the alternatives to the pesticide use pose greater risks to the environment or human health;

(C) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

(mm) Antimicrobial pesticide

(1) In general

The term "antimicrobial pesticide" means a pesticide that--

(A) is intended to--

(i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or

(ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 346a of Title 21 or a food additive regulation under section 348 of Title 21.

(2) Excluded products

The term "antimicrobial pesticide" does not include--

(A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;

(B) an agricultural fungicide product; or

(C) an aquatic herbicide product.

(3) Included products

The term "antimicrobial pesticide" does include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u)), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).

(nn) Public health pesticide

The term "public health pesticide" means any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health.

(oo) Vector

The term "vector" means any organism capable of transmitting the causative agent of human disease or capable of producing human discomfort or injury, including mosquitoes, flies, fleas, cockroaches, or other insects and ticks, mites, or rats.

CREDIT(S)

(June 25, 1947, c. 125, § 2, as added Pub.L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 975; amended Pub.L. 93-205, § 13(f), Dec. 28, 1973, 87 Stat. 903; Pub.L. 94-140, § 9, Nov. 28, 1975, 89 Stat. 754; Pub.L. 95-396, § 1, Sept. 30, 1978, 92 Stat. 819; Pub.L. 100-532, Title I, § 101, Title VI, § 601(a), Title VIII, § 801(a), Oct. 25, 1988, 102 Stat. 2655, 2677, 2679; Pub.L. 102-237, Title X, § 1006(a)(1), (2), (b)(3)(A), (B), Dec. 13, 1991, 105 Stat. 1894, 1895; Pub.L. 104-170, Title I, §§ 105(a), 120, Title II, §§ 210(a), 221, 230, Title III, § 304, Aug. 3, 1996, 110 Stat. 1490, 1492, 1493, 1502, 1508, 1512.)

Notes of Decisions (11)

Footnotes

1 So in original. Probably should not have a period.

2 So in original. Probably should be followed by ", or".

3 So in original. No subsec. (ii) has been enacted.

7 U.S.C.A. § 136, 7 USCA § 136
Current through P.L. 117-159. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 6. Insecticides and Environmental Pesticide Control (Refs & Annos)
Subchapter II. Environmental Pesticide Control (Refs & Annos)

7 U.S.C.A. § 136a

§ 136a. Registration of pesticides

Effective: December 20, 2018
Currentness

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

(b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if--

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes--

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that--

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the

date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

(v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after August 3, 1996, except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

(vi) With respect to data submitted after August 3, 1996, by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are

subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

(2) Data in support of registration

(A) In general

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

(B) Additional data

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration

proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 136a-1 of this title for the other uses of the pesticide established as of August 3, 1996, if--

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 136a-1 of this title; and

(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under section 136a-1 of this title for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after August 3, 1996, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) Simplified procedures

Within nine months after September 30, 1978, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption

No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to--

(i) submit or cite data pertaining to such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) Minor use waiver

In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining--

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

(3) Application

(A) In general

The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the subchapter in accordance with paragraph (6).

(B) Identical or substantially similar

(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that--

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall--

(I) review the application in accordance with section 136w-8(f)(4)(B) of this title and, if the application is found to be incomplete, reject the application;

(II) not later than the applicable decision review time established pursuant to section 136w-8(f)(4)(B) of this title, or, if no review time is established, not later than 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

(C) Minor use registration

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application--

(I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

(II) for a registration or a registration amendment that proposes significant minor uses.

(ii) For the purposes of clause (i)--

(I) the term "as expeditiously as possible" means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and

(II) the term "significant minor uses" means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 136p of this title for that minor use.

(D) Adequate time for submission of minor use data

If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term "full-time period" means the time period

originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

(4) Notice of application

The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d)--

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

(6) Denial of registration

If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 136d of this title.

(7) Registration under special circumstances

Notwithstanding the provisions of paragraph (5)--

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

(8) Interim administrative review

Notwithstanding any other provision of this subchapter, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this subchapter, unless such interim

administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.

(9) Labeling

(A) Additional statements

Subject to subparagraphs (B) and (C), it shall not be a violation of this subchapter for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) Requirements

Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

(C) Notification and disapproval

(i) Notification

A registration may be modified under subparagraph (A) if--

(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

(II) the Administrator does not disapprove of the modification under clause (ii).

(ii) Disapproval

Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

(iii) Restriction on sale

A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) Objection

A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

(v) Final action

A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

(D) Use dilution

The label or labeling required under this subchapter for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that--

(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

(10) Expedited registration of pesticides

(A) Not later than 1 year after August 3, 1996, the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

(i) Reduce the risks of pesticides to human health.

(ii) Reduce the risks of pesticides to nontarget organisms.

(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

(11) Interagency working group

(A) Definition of covered agency

In this paragraph, the term "covered agency" means any of the following:

(i) The Department of Agriculture.

(ii) The Department of Commerce.

(iii) The Department of the Interior.

(iv) The Council on Environmental Quality.

(v) The Environmental Protection Agency.

(B) Establishment

The Administrator shall establish an interagency working group, to be comprised of representatives from each covered agency, to provide recommendations regarding, and to implement a strategy for improving, the consultation process required under section 7 of the Endangered Species Act of 1973 (16 U.S.C. 1536) for pesticide registration and registration review.

(C) Duties

The interagency working group established under subparagraph (B) shall--

(i) analyze relevant Federal law (including regulations) and case law for purposes of providing an outline of the legal and regulatory framework for the consultation process referred to in that subparagraph, including--

(I) requirements under this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.);

(II) Federal case law regarding the intersection of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.); and

(III) Federal regulations relating to the pesticide consultation process;

(ii) provide advice regarding methods of--

(I) defining the scope of actions of the covered agencies that are subject to the consultation requirement referred to in subparagraph (B); and

(II) properly identifying and classifying effects of actions of the covered agencies with respect to that consultation requirement;

(iii) identify the obligations and limitations under Federal law of each covered agency for purposes of providing a legal and regulatory framework for developing the recommendations referred to in subparagraph (B);

(iv) review practices for the consultation referred to in subparagraph (B) to identify problem areas, areas for improvement, and best practices for conducting that consultation among the covered agencies;

(v) develop scientific and policy approaches to increase the accuracy and timeliness of the process for that consultation, in accordance with requirements of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including--

(I) processes to efficiently share data and coordinate analyses among the Department of Agriculture, the Department of Commerce, the Department of the Interior, and the Environmental Protection Agency;

(II) a streamlined process for identifying which actions require no consultation, informal consultation, or formal consultation;

(III) an approach that will provide clarity with respect to what constitutes the best scientific and commercial data available in the fields of pesticide use and ecological risk assessment, pursuant to section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1536(a)(2)); and

(IV) approaches that enable the Environmental Protection Agency to better assist the Department of the Interior and the Department of Commerce in carrying out obligations under that section in a timely and efficient manner; and

(vi) propose and implement a strategy to implement approaches to consultations under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) and document that strategy in a memorandum of understanding, revised regulations, or another appropriate format to promote durable cooperation among the covered agencies.

(D) Reports

(i) Progress reports

(I) In general

Not later than 18 months after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing the progress of the working group in developing the recommendations under subparagraph (B).

(II) Requirements

The report under this clause shall--

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of new consensus and continuing topics of disagreement and debate.

(ii) Results

(I) In general

Not later than 1 year after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing--

(aa) the recommendations developed under subparagraph (B); and

(bb) plans for implementation of those recommendations.

(II) Requirements

The report under this clause shall--

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of consensus and continuing topics of disagreement and debate, if any.

(iii) Implementation

Not later than 1 year after the date of submission of the report under clause (i), the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing--

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(iv) Other reports

Not later than the date that is 180 days after the date of submission of the report under clause (iii), and not less frequently than once every 180 days thereafter during the 5-year period beginning on that date, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing--

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(E) Consultation with private sector

In carrying out the duties under this paragraph, the working group shall, as appropriate--

(i) consult with, representatives of interested industry stakeholders and nongovernmental organizations; and

(ii) take into consideration factors, such as actual and potential differences in interest between, and the views of, those stakeholders and organizations.

(F) Federal Advisory Committee Act

The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the working group established under this paragraph.

(G) Savings clause

Nothing in this paragraph supersedes any provision of--

(i) this subchapter; or

(ii) the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including the requirements under section 7 of that Act (16 U.S.C. 1536).

(d) Classification of pesticides

(1) Classification for general use, restricted use, or both

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use, and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) Change in classification

If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 136d(b) of this title.

(3) Change in classification from restricted use to general use

The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 136n of this title.

(e) Products with same formulation and claims

Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(f) Miscellaneous

(1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

(3) Authority to consult other Federal agencies

In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

(4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of--

(A) 1 or more nitrogen stabilizers registered under this subchapter; and

(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 136a-1, 136c, 136e, 136m, and 136*o*(a)(2) of this title if the mixture or other combination is accompanied by the labeling required under this subchapter for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) Initial registration review

The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of--

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

(v) Cancellation

No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title.

(B) Docketing

(i) In general

Subject to clause (ii), after meeting with 1 or more individuals that are not government employees to discuss matters relating to a registration review, the Administrator shall place in the docket minutes of the meeting, a list of attendees, and any documents exchanged at the meeting, not later than the earlier of--

(I) the date that is 45 days after the meeting; or

(II) the date of issuance of the registration review decision.

(ii) Protected information

The Administrator shall identify, but not include in the docket, any confidential business information the disclosure of which is prohibited by section 136h of this title.

(C) Limitation

Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this subchapter.

(2) Data

(A) Submission required

The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.

(B) Data submission, compensation, and exemption

For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applicable to any data required for registration review.

(h) Registration requirements for antimicrobial pesticides

(1) Evaluation of process

To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of August 3, 1996, for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including--

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal

Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than--

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

(C) 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) Implementation

(A) Proposed rulemaking

(i) Issuance

Not later than 270 days after August 3, 1996, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) Requirements

Proposed regulations issued under clause (i) shall--

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this subchapter, considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) Comments

In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) Final regulations

(i) Issuance

The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) Failure to meet goal

If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) Requirements

In issuing final regulations, the Administrator shall--

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including--

(aa) expanded use of notification and non-notification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

(C) Expedited review

This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3).

(D) Alternative review periods

If the final regulations to carry out this paragraph are not effective 630 days after August 3, 1996, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be--

(i) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(vi) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) Wood preservatives

An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 136(mm) of this title is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) Notification

(i) In general

Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) Final decision

If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of Title 5.

(iii) Exemption

This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) prior to 90 days after August 3, 1996.

(iv) Limitation

Notwithstanding clause (ii), the failure of the Administrator to notify an applicant for an amendment to a registration for an antimicrobial pesticide shall not be judicially reviewable in a Federal or State court if the amendment requires scientific review of data within--

(I) the time period specified in subparagraph (D)(vi), in the absence of a final regulation under subparagraph (B); or

(II) the time period specified in paragraph (2)(F), if adopted in a final regulation under subparagraph (B).

(4) Annual report

(A) Submission

Beginning on August 3, 1996, and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) Requirements

A report submitted under subparagraph (A) shall include a description of--

(i) measures taken to reduce the backlog of pending registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

CREDIT(S)

(June 25, 1947, c. 125, § 3, as added Pub.L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 979; amended Pub.L. 94-140, § 12, Nov. 28, 1975, 89 Stat. 755; Pub.L. 95-396, §§ 2(a), 3-8, Sept. 30, 1978, 92 Stat. 820, 824-827; Pub.L. 100-532, Title I, §§ 102(b), 103, Title VI, § 601(b)(1), Title VIII, § 801(b), Oct. 25, 1988, 102 Stat. 2667, 2677, 2680; Pub.L. 101-624, Title XIV, § 1492, Nov. 28, 1990, 104 Stat. 3628; Pub.L. 102-237, Title X, § 1006(a)(3), (b)(1), (2), (c), Dec. 13, 1991, 105 Stat. 1894 to 1896; Pub.L. 104-170, Title I, §§ 105(b), 106(b), Title II, §§ 210(b), (c)(1), (d), (e), (f)(2), 222 to 224, 231, 250, Aug. 3, 1996, 110 Stat. 1491, 1494 to 1497, 1499, 1503, 1504, 1508, 1510; Pub.L. 108-199, Div. G, Title V, § 501(b), Jan. 23, 2004, 118 Stat. 419; Pub.L. 110-94, §§ 2, 3, Oct. 9, 2007, 121 Stat. 1000; Pub.L. 115-334, Title X, § 10115, Dec. 20, 2018, 132 Stat. 4914.)

Notes of Decisions (119)

7 U.S.C.A. § 136a, 7 USCA § 136a
Current through P.L. 117-159. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 6. Insecticides and Environmental Pesticide Control (Refs & Annos)
Subchapter II. Environmental Pesticide Control (Refs & Annos)

7 U.S.C.A. § 136n

§ 136n. Administrative procedure; judicial review

Currentness

(a) District court review

Except as otherwise provided in this subchapter, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.

(b) Review by court of appeals

In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the Administrator's order, as provided in section 2112 of Title 28. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of Title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

(c) Jurisdiction of district courts

The district courts of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this subchapter.

(d) Notice of judgments

The Administrator shall, by publication in such manner as the Administrator may prescribe, give notice of all judgments entered in actions instituted under the authority of this subchapter.

CREDIT(S)

(June 25, 1947, c. 125, § 16, as added Pub.L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 994; amended Pub.L. 98-620, Title IV, § 402(4)(C), Nov. 8, 1984, 98 Stat. 3357; Pub.L. 100-532, Title VIII, § 801(i), Oct. 25, 1988, 102 Stat. 2682; Pub.L. 102-237, Title X, § 1006(b)(1), (2), (3)(P), Dec. 13, 1991, 105 Stat. 1895, 1896.)

Notes of Decisions (73)

7 U.S.C.A. § 136n, 7 USCA § 136n
Current through P.L. 117-159. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 16. Conservation
Chapter 35. Endangered Species (Refs & Annos)

16 U.S.C.A. § 1536

§ 1536. Interagency cooperation

Currentness

(a) Federal agency actions and consultations

(1) The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this chapter. All other Federal agencies shall, in consultation with and with the assistance of the Secretary, utilize their authorities in furtherance of the purposes of this chapter by carrying out programs for the conservation of endangered species and threatened species listed pursuant to section 1533 of this title.

(2) Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency (hereinafter in this section referred to as an "agency action") is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary, after consultation as appropriate with affected States, to be critical, unless such agency has been granted an exemption for such action by the Committee pursuant to subsection (h) of this section. In fulfilling the requirements of this paragraph each agency shall use the best scientific and commercial data available.

(3) Subject to such guidelines as the Secretary may establish, a Federal agency shall consult with the Secretary on any prospective agency action at the request of, and in cooperation with, the prospective permit or license applicant if the applicant has reason to believe that an endangered species or a threatened species may be present in the area affected by his project and that implementation of such action will likely affect such species.

(4) Each Federal agency shall confer with the Secretary on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under section 1533 of this title or result in the destruction or adverse modification of critical habitat proposed to be designated for such species. This paragraph does not require a limitation on the commitment of resources as described in subsection (d).

(b) Opinion of Secretary

(1)(A) Consultation under subsection (a)(2) with respect to any agency action shall be concluded within the 90-day period beginning on the date on which initiated or, subject to subparagraph (B), within such other period of time as is mutually agreeable to the Secretary and the Federal agency.

(B) In the case of an agency action involving a permit or license applicant, the Secretary and the Federal agency may not mutually agree to conclude consultation within a period exceeding 90 days unless the Secretary, before the close of the 90th day referred to in subparagraph (A)--

(i) if the consultation period proposed to be agreed to will end before the 150th day after the date on which consultation was initiated, submits to the applicant a written statement setting forth--

(I) the reasons why a longer period is required,

(II) the information that is required to complete the consultation, and

(III) the estimated date on which consultation will be completed; or

(ii) if the consultation period proposed to be agreed to will end 150 or more days after the date on which consultation was initiated, obtains the consent of the applicant to such period.

The Secretary and the Federal agency may mutually agree to extend a consultation period established under the preceding sentence if the Secretary, before the close of such period, obtains the consent of the applicant to the extension.

(2) Consultation under subsection (a)(3) shall be concluded within such period as is agreeable to the Secretary, the Federal agency, and the applicant concerned.

(3)(A) Promptly after conclusion of consultation under paragraph (2) or (3) of subsection (a), the Secretary shall provide to the Federal agency and the applicant, if any, a written statement setting forth the Secretary's opinion, and a summary of the information on which the opinion is based, detailing how the agency action affects the species or its critical habitat. If jeopardy or adverse modification is found, the Secretary shall suggest those reasonable and prudent alternatives which he believes would not violate subsection (a)(2) and can be taken by the Federal agency or applicant in implementing the agency action.

(B) Consultation under subsection (a)(3), and an opinion issued by the Secretary incident to such consultation, regarding an agency action shall be treated respectively as a consultation under subsection (a)(2), and as an opinion issued after consultation under such subsection, regarding that action if the Secretary reviews the action before it is commenced by the Federal agency and finds, and notifies such agency, that no significant changes have been made with respect to the action and that no significant change has occurred regarding the information used during the initial consultation.

(4) If after consultation under subsection (a)(2), the Secretary concludes that--

(A) the agency action will not violate such subsection, or offers reasonable and prudent alternatives which the Secretary believes would not violate such subsection;

(B) the taking of an endangered species or a threatened species incidental to the agency action will not violate such subsection; and

(C) if an endangered species or threatened species of a marine mammal is involved, the taking is authorized pursuant to section 1371(a)(5) of this title;

the Secretary shall provide the Federal agency and the applicant concerned, if any, with a written statement that--

(i) specifies the impact of such incidental taking on the species,

(ii) specifies those reasonable and prudent measures that the Secretary considers necessary or appropriate to minimize such impact,

(iii) in the case of marine mammals, specifies those measures that are necessary to comply with section 1371(a)(5) of this title with regard to such taking, and

(iv) sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or applicant (if any), or both, to implement the measures specified under clauses (ii) and (iii).

(c) Biological assessment

(1) To facilitate compliance with the requirements of subsection (a)(2), each Federal agency shall, with respect to any agency action of such agency for which no contract for construction has been entered into and for which no construction has begun on November 10, 1978, request of the Secretary information whether any species which is listed or proposed to be listed may be present in the area of such proposed action. If the Secretary advises, based on the best scientific and commercial data available, that such species may be present, such agency shall conduct a biological assessment for the purpose of identifying any endangered species or threatened species which is likely to be affected by such action. Such assessment shall be completed within 180 days after the date on which initiated (or within such other period as is mutually agreed to by the Secretary and such agency, except that if a permit or license applicant is involved, the 180-day period may not be extended unless such agency provides the applicant, before the close of such period, with a written statement setting forth the estimated length of the proposed extension and the reasons therefor) and, before any contract for construction is entered into and before construction is begun with respect to such action. Such assessment may be undertaken as part of a Federal agency's compliance with the requirements of section 102 of the National Environmental Policy Act of 1969 (42 U.S.C. 4332).

(2) Any person who may wish to apply for an exemption under subsection (g) of this section for that action may conduct a biological assessment to identify any endangered species or threatened species which is likely to be affected by such action. Any such biological assessment must, however, be conducted in cooperation with the Secretary and under the supervision of the appropriate Federal agency.

(d) Limitation on commitment of resources

After initiation of consultation required under subsection (a)(2), the Federal agency and the permit or license applicant shall not make any irreversible or irretrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures which would not violate subsection (a)(2) of this section.

(e) Endangered Species Committee

(1) There is established a committee to be known as the Endangered Species Committee (hereinafter in this section referred to as the "Committee").

(2) The Committee shall review any application submitted to it pursuant to this section and determine in accordance with subsection (h) of this section whether or not to grant an exemption from the requirements of subsection (a)(2) of this section for the action set forth in such application.

(3) The Committee shall be composed of seven members as follows:

(A) The Secretary of Agriculture.

(B) The Secretary of the Army.

(C) The Chairman of the Council of Economic Advisors.

(D) The Administrator of the Environmental Protection Agency.

(E) The Secretary of the Interior.

(F) The Administrator of the National Oceanic and Atmospheric Administration.

(G) The President, after consideration of any recommendations received pursuant to subsection (g)(2)(B) shall appoint one individual from each affected State, as determined by the Secretary, to be a member of the Committee for the consideration of the application for exemption for an agency action with respect to which such recommendations are made, not later than 30 days after an application is submitted pursuant to this section.

(4)(A) Members of the Committee shall receive no additional pay on account of their service on the Committee.

(B) While away from their homes or regular places of business in the performance of services for the Committee, members of the Committee shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703 of Title 5.

(5)(A) Five members of the Committee or their representatives shall constitute a quorum for the transaction of any function of the Committee, except that, in no case shall any representative be considered in determining the existence of a quorum for the transaction of any function of the Committee if that function involves a vote by the Committee on any matter before the Committee.

(B) The Secretary of the Interior shall be the Chairman of the Committee.

(C) The Committee shall meet at the call of the Chairman or five of its members.

(D) All meetings and records of the Committee shall be open to the public.

(6) Upon request of the Committee, the head of any Federal agency is authorized to detail, on a nonreimbursable basis, any of the personnel of such agency to the Committee to assist it in carrying out its duties under this section.

(7)(A) The Committee may for the purpose of carrying out its duties under this section hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Committee deems advisable.

(B) When so authorized by the Committee, any member or agent of the Committee may take any action which the Committee is authorized to take by this paragraph.

(C) Subject to the Privacy Act, the Committee may secure directly from any Federal agency information necessary to enable it to carry out its duties under this section. Upon request of the Chairman of the Committee, the head of such Federal agency shall furnish such information to the Committee.

(D) The Committee may use the United States mails in the same manner and upon the same conditions as a Federal agency.

(E) The Administrator of General Services shall provide to the Committee on a reimbursable basis such administrative support services as the Committee may request.

(8) In carrying out its duties under this section, the Committee may promulgate and amend such rules, regulations, and procedures, and issue and amend such orders as it deems necessary.

(9) For the purpose of obtaining information necessary for the consideration of an application for an exemption under this section the Committee may issue subpenas for the attendance and testimony of witnesses and the production of relevant papers, books, and documents.

(10) In no case shall any representative, including a representative of a member designated pursuant to paragraph (3)(G) of this subsection, be eligible to cast a vote on behalf of any member.

(f) Promulgation of regulations; form and contents of exemption application

Not later than 90 days after November 10, 1978, the Secretary shall promulgate regulations which set forth the form and manner in which applications for exemption shall be submitted to the Secretary and the information to be contained in such applications.

Such regulations shall require that information submitted in an application by the head of any Federal agency with respect to any agency action include, but not be limited to--

(1) a description of the consultation process carried out pursuant to subsection (a)(2) of this section between the head of the Federal agency and the Secretary; and

(2) a statement describing why such action cannot be altered or modified to conform with the requirements of subsection (a)(2) of this section.

(g) Application for exemption; report to Committee

(1) A Federal agency, the Governor of the State in which an agency action will occur, if any, or a permit or license applicant may apply to the Secretary for an exemption for an agency action of such agency if, after consultation under subsection (a)(2), the Secretary's opinion under subsection (b) indicates that the agency action would violate subsection (a)(2). An application for an exemption shall be considered initially by the Secretary in the manner provided for in this subsection, and shall be considered by the Committee for a final determination under subsection (h) after a report is made pursuant to paragraph (5). The applicant for an exemption shall be referred to as the "exemption applicant" in this section.

(2)(A) An exemption applicant shall submit a written application to the Secretary, in a form prescribed under subsection (f), not later than 90 days after the completion of the consultation process; except that, in the case of any agency action involving a permit or license applicant, such application shall be submitted not later than 90 days after the date on which the Federal agency concerned takes final agency action with respect to the issuance of the permit or license. For purposes of the preceding sentence, the term "final agency action" means (i) a disposition by an agency with respect to the issuance of a permit or license that is subject to administrative review, whether or not such disposition is subject to judicial review; or (ii) if administrative review is sought with respect to such disposition, the decision resulting after such review. Such application shall set forth the reasons why the exemption applicant considers that the agency action meets the requirements for an exemption under this subsection.

(B) Upon receipt of an application for exemption for an agency action under paragraph (1), the Secretary shall promptly (i) notify the Governor of each affected State, if any, as determined by the Secretary, and request the Governors so notified to recommend individuals to be appointed to the Endangered Species Committee for consideration of such application; and (ii) publish notice of receipt of the application in the Federal Register, including a summary of the information contained in the application and a description of the agency action with respect to which the application for exemption has been filed.

(3) The Secretary shall within 20 days after the receipt of an application for exemption, or within such other period of time as is mutually agreeable to the exemption applicant and the Secretary--

(A) determine that the Federal agency concerned and the exemption applicant have--

(i) carried out the consultation responsibilities described in subsection (a) in good faith and made a reasonable and responsible effort to develop and fairly consider modifications or reasonable and prudent alternatives to the proposed agency action which would not violate subsection (a)(2);

(ii) conducted any biological assessment required by subsection (c); and

(iii) to the extent determinable within the time provided herein, refrained from making any irreversible or irretrievable commitment of resources prohibited by subsection (d); or

(B) deny the application for exemption because the Federal agency concerned or the exemption applicant have not met the requirements set forth in subparagraph (A)(i), (ii), and (iii).

The denial of an application under subparagraph (B) shall be considered final agency action for purposes of chapter 7 of Title 5.

(4) If the Secretary determines that the Federal agency concerned and the exemption applicant have met the requirements set forth in paragraph (3)(A)(i), (ii), and (iii) he shall, in consultation with the Members of the Committee, hold a hearing on the application for exemption in accordance with sections 554, 555, and 556 (other than subsection (b)(1) and (2) thereof) of Title 5 and prepare the report to be submitted pursuant to paragraph (5).

(5) Within 140 days after making the determinations under paragraph (3) or within such other period of time as is mutually agreeable to the exemption applicant and the Secretary, the Secretary shall submit to the Committee a report discussing--

(A) the availability of reasonable and prudent alternatives to the agency action, and the nature and extent of the benefits of the agency action and of alternative courses of action consistent with conserving the species or the critical habitat;

(B) a summary of the evidence concerning whether or not the agency action is in the public interest and is of national or regional significance;

(C) appropriate reasonable mitigation and enhancement measures which should be considered by the Committee; and

(D) whether the Federal agency concerned and the exemption applicant refrained from making any irreversible or irretrievable commitment of resources prohibited by subsection (d).

(6) To the extent practicable within the time required for action under subsection (g) of this section, and except to the extent inconsistent with the requirements of this section, the consideration of any application for an exemption under this section and the conduct of any hearing under this subsection shall be in accordance with sections 554, 555, and 556 (other than subsection (b)(3) of section 556) of Title 5.

(7) Upon request of the Secretary, the head of any Federal agency is authorized to detail, on a nonreimbursable basis, any of the personnel of such agency to the Secretary to assist him in carrying out his duties under this section.

(8) All meetings and records resulting from activities pursuant to this subsection shall be open to the public.

(h) Grant of exemption

(1) The Committee shall make a final determination whether or not to grant an exemption within 30 days after receiving the report of the Secretary pursuant to subsection (g)(5). The Committee shall grant an exemption from the requirements of subsection (a)(2) for an agency action if, by a vote of not less than five of its members voting in person--

(A) it determines on the record, based on the report of the Secretary, the record of the hearing held under subsection (g)(4) and on such other testimony or evidence as it may receive, that--

(i) there are no reasonable and prudent alternatives to the agency action;

(ii) the benefits of such action clearly outweigh the benefits of alternative courses of action consistent with conserving the species or its critical habitat, and such action is in the public interest;

(iii) the action is of regional or national significance; and

(iv) neither the Federal agency concerned nor the exemption applicant made any irreversible or irretrievable commitment of resources prohibited by subsection (d); and

(B) it establishes such reasonable mitigation and enhancement measures, including, but not limited to, live propagation, transplantation, and habitat acquisition and improvement, as are necessary and appropriate to minimize the adverse effects of the agency action upon the endangered species, threatened species, or critical habitat concerned.

Any final determination by the Committee under this subsection shall be considered final agency action for purposes of chapter 7 of Title 5.

(2)(A) Except as provided in subparagraph (B), an exemption for an agency action granted under paragraph (1) shall constitute a permanent exemption with respect to all endangered or threatened species for the purposes of completing such agency action--

(i) regardless whether the species was identified in the biological assessment; and

(ii) only if a biological assessment has been conducted under subsection (c) with respect to such agency action.

(B) An exemption shall be permanent under subparagraph (A) unless--

(i) the Secretary finds, based on the best scientific and commercial data available, that such exemption would result in the extinction of a species that was not the subject of consultation under subsection (a)(2) or was not identified in any biological assessment conducted under subsection (c), and

(ii) the Committee determines within 60 days after the date of the Secretary's finding that the exemption should not be permanent.

If the Secretary makes a finding described in clause (i), the Committee shall meet with respect to the matter within 30 days after the date of the finding.

(i) Review by Secretary of State; violation of international treaty or other international obligation of United States

Notwithstanding any other provision of this chapter, the Committee shall be prohibited from considering for exemption any application made to it, if the Secretary of State, after a review of the proposed agency action and its potential implications, and after hearing, certifies, in writing, to the Committee within 60 days of any application made under this section that the granting of any such exemption and the carrying out of such action would be in violation of an international treaty obligation or other international obligation of the United States. The Secretary of State shall, at the time of such certification, publish a copy thereof in the Federal Register.

(j) Exemption for national security reasons

Notwithstanding any other provision of this chapter, the Committee shall grant an exemption for any agency action if the Secretary of Defense finds that such exemption is necessary for reasons of national security.

(k) Exemption decision not considered major Federal action; environmental impact statement

An exemption decision by the Committee under this section shall not be a major Federal action for purposes of the National Environmental Policy Act of 1969: *Provided*, That an environmental impact statement which discusses the impacts upon endangered species or threatened species or their critical habitats shall have been previously prepared with respect to any agency action exempted by such order.

(l) Committee order granting exemption; cost of mitigation and enhancement measures; report by applicant to Council on Environmental Quality

(1) If the Committee determines under subsection (h) that an exemption should be granted with respect to any agency action, the Committee shall issue an order granting the exemption and specifying the mitigation and enhancement measures established pursuant to subsection (h) which shall be carried out and paid for by the exemption applicant in implementing the agency action. All necessary mitigation and enhancement measures shall be authorized prior to the implementing of the agency action and funded concurrently with all other project features.

(2) The applicant receiving such exemption shall include the costs of such mitigation and enhancement measures within the overall costs of continuing the proposed action. Notwithstanding the preceding sentence the costs of such measures shall not be treated as project costs for the purpose of computing benefit-cost or other ratios for the proposed action. Any applicant may request the Secretary to carry out such mitigation and enhancement measures. The costs incurred by the Secretary in carrying out any such measures shall be paid by the applicant receiving the exemption. No later than one year after the granting of an exemption, the exemption applicant shall submit to the Council on Environmental Quality a report describing its compliance with the mitigation and enhancement measures prescribed by this section. Such a report shall be submitted annually until all such mitigation and enhancement measures have been completed. Notice of the public availability of such reports shall be published in the Federal Register by the Council on Environmental Quality.

(m) Notice requirement for citizen suits not applicable

The 60-day notice requirement of section 1540(g) of this title shall not apply with respect to review of any final determination of the Committee under subsection (h) of this section granting an exemption from the requirements of subsection (a)(2) of this section.

(n) Judicial review

Any person, as defined by section 1532(13) of this title, may obtain judicial review, under chapter 7 of Title 5, of any decision of the Endangered Species Committee under subsection (h) in the United States Court of Appeals for (1) any circuit wherein the agency action concerned will be, or is being, carried out, or (2) in any case in which the agency action will be, or is being, carried out outside of any circuit, the District of Columbia, by filing in such court within 90 days after the date of issuance of the decision, a written petition for review. A copy of such petition shall be transmitted by the clerk of the court to the Committee and the Committee shall file in the court the record in the proceeding, as provided in section 2112 of Title 28. Attorneys designated by the Endangered Species Committee may appear for, and represent the Committee in any action for review under this subsection.

(o) Exemption as providing exception on taking of endangered species

Notwithstanding sections 1533(d) and 1538(a)(1)(B) and (C) of this title, sections 1371 and 1372 of this title, or any regulation promulgated to implement any such section--

(1) any action for which an exemption is granted under subsection (h) shall not be considered to be a taking of any endangered species or threatened species with respect to any activity which is necessary to carry out such action; and

(2) any taking that is in compliance with the terms and conditions specified in a written statement provided under subsection (b)(4)(iv) shall not be considered to be a prohibited taking of the species concerned.

(p) Exemptions in Presidentially declared disaster areas

In any area which has been declared by the President to be a major disaster area under the Disaster Relief and Emergency Assistance Act, the President is authorized to make the determinations required by subsections (g) and (h) of this section for any project for the repair or replacement of a public facility substantially as it existed prior to the disaster under section 405 or 406 of the Disaster Relief and Emergency Assistance Act, and which the President determines (1) is necessary to prevent the recurrence of such a natural disaster and to reduce the potential loss of human life, and (2) to involve an emergency situation which does not allow the ordinary procedures of this section to be followed. Notwithstanding any other provision of this section, the Committee shall accept the determinations of the President under this subsection.

CREDIT(S)

(Pub.L. 93-205, § 7, Dec. 28, 1973, 87 Stat. 892; Pub.L. 95-632, § 3, Nov. 10, 1978, 92 Stat. 3752; Pub.L. 96-159, § 4, Dec. 28, 1979, 93 Stat. 1226; Pub.L. 97-304, §§ 4(a), 8(b), Oct. 13, 1982, 96 Stat. 1417, 1426; Pub.L. 99-659, Title IV, § 411(b), (c), Nov. 14, 1986, 100 Stat. 3742; Pub.L. 100-707, Title I, § 109(g), Nov. 23, 1988, 102 Stat. 4709.)

Notes of Decisions (889)

16 U.S.C.A. § 1536, 16 USCA § 1536
Current through P.L. 117-159. Some statute sections may be more current, see credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter A. General
Part 23. Judicial Review Under EPA—Administered Statutes (Refs & Annos)

40 C.F.R. § 23.6

§ 23.6 Timing of Administrator's action under Federal Insecticide, Fungicide and Rodenticide Act.

Currentness

Unless the Administrator otherwise explicitly provides in a particular order, the time and date of entry of an order issued by the Administrator following a public hearing for purposes of section 16(b) shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is two weeks after it is signed.

SOURCE: 50 FR 7270, Feb. 21, 1985; 53 FR 29322, Aug. 3, 1988; 70 FR 33359, June 8, 2005, unless otherwise noted.

AUTHORITY: Clean Water Act, 33 U.S.C. 1361(a), 1369(b); Clean Air Act, 42 U.S.C. 7601(a)(1), 7607(b); Resource, Conservation and Recovery Act, 42 U.S.C. 6912(a), 6976; Toxic Substances Control Act, 15 U.S.C. 2618; Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136n(b), 136w(a); Safe Drinking Water Act, 42 U.S.C. 300j–7(a)(2), 300j–9(a); Atomic Energy Act, 42 U.S.C. 2201, 2239; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), 346a, 28 U.S.C. 2112(a), 2343, 2344.

Current through July1, 2022, 87 FR 39677. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 152. Pesticide Registration and Classification Procedures (Refs & Annos)
Subpart C. Registration Procedures (Refs & Annos)

40 C.F.R. § 152.44

§ 152.44 Application for amended registration.

Currentness

(a) Except as provided by § 152.46, any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration. The applicant must submit the information required by § 152.50, as applicable to the change requested. If an application for amended registration is required, the application must be approved by the Agency before the product, as modified, may legally be distributed or sold.

(b) In its discretion, the Agency may:

(1) Waive the requirement for submission of an application for amended registration;

(2) Require that the applicant certify to the Agency that he has complied with an Agency directive rather than submit an application for amended registration; or

(3) Permit an applicant to modify a registration by notification or non-notification in accordance with § 152.46.

(c) A registrant may at any time submit identical minor labeling amendments affecting a number of products as a single application if no data are required for EPA to approve the amendment (for example, a change in the wording of a storage statement for designated residential use products). A consolidated application must clearly identify the labeling modification(s) to be made (which must be identical for all products included in the application), list the registration number of each product for which the modification is requested, and provide required supporting materials (for example, labeling) for each affected product.

Credits
[61 FR 33041, June 26, 1996; 66 FR 64764, Dec. 14, 2001]

SOURCE: 49 FR 30903, Aug. 1, 1984; 50 FR 16234, April 25, 1985; 50 FR 41143, Oct. 9, 1985; 53 FR 15978, May 4, 1988; 53 FR 19114, May 26, 1988; 53 FR 30431, Aug. 12, 1988; 54 FR 11923, March 22, 1989, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136–136y; Subpart U is also issued under 31 U.S.C. 9701.

Current through July1, 2022, 87 FR 39677. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 152. Pesticide Registration and Classification Procedures (Refs & Annos)
Subpart F. Agency Review of Applications (Refs & Annos)

40 C.F.R. § 152.112

§ 152.112 Approval of registration under FIFRA sec. 3(c)(5).

Effective: February 10, 2009
Currentness

EPA will approve an application under the criteria of FIFRA sec. 3(c)(5) only if:

(a) The Agency has determined that the application is complete and is accompanied by all materials required by the Act and this part, including, but not limited to, evidence of compliance with subpart E of this part;

(b) The Agency has reviewed all relevant data in the possession of the Agency (see §§ 152.107 and 152.111);

(c) The Agency has determined that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5) with respect to the pesticide product which is the subject of the application;

(d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted for the product by part 158 or part 161 of this chapter, as applicable.

(e) The Agency has determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;

(f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter;

(g) If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA sec. 408, and

(h) If the product, in addition to being a pesticide, is a drug within the meaning of FFDCA sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.

Credits

[72 FR 61028, Oct. 26, 2007; 73 FR 75595, Dec. 12, 2008]

SOURCE: 49 FR 30903, Aug. 1, 1984; 50 FR 16234, April 25, 1985; 50 FR 41143, Oct. 9, 1985; 53 FR 15980, May 4, 1988; 53 FR 19114, May 26, 1988; 53 FR 30431, Aug. 12, 1988; 54 FR 11923, March 22, 1989, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136–136y; Subpart U is also issued under 31 U.S.C. 9701.

Notes of Decisions (34)

Current through July1, 2022, 87 FR 39677. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 158. Data Requirements for Pesticides (Refs & Annos)
Subpart A. General Provisions

40 C.F.R. § 158.75

§ 158.75 Requirements for additional data.

Effective: December 26, 2007
Currentness

The data routinely required by this part may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties and effects of the pesticide.

SOURCE: 72 FR 60957, Oct. 26, 2007, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136 - 136y; 21 U.S.C. 346a.

Current through July1, 2022, 87 FR 39677. Some sections may be more current. See credits for details.

End of Document

40 C.F.R. § 158.110

§ 158.110 Required and conditionally required data.

Effective: December 26, 2007
Currentness

The tables in this part use the descriptors R (required), CR (conditionally required), and NR (not required) as a general indication of the applicability of a data requirement. In all cases, the test notes referred to in the table must be consulted to determine the actual applicability of the data requirement.

(a) EPA requires data designated as “required”(R) for products with a given use pattern in order to evaluate the risks or benefits of a product having that use pattern under any conditions established by the test notes.

(b) Data designated as “conditionally required” (CR) for products with a given use pattern are required by EPA to evaluate the risks or benefits of a product having that use pattern if the product meets the conditions specified in the notes accompanying the requirement. The determination of whether the data must be submitted is based on the product's use pattern, physical or chemical properties, expected exposure of nontarget organisms, and/or results of previous testing (for example, tier testing). Applicants must evaluate each applicable test note for the conditions and criteria to be considered in determining whether conditionally required data must be submitted.

(c) Data not required for the Agency's assessment of the risks and benefits of a particular use pattern are designated “not required” (NR) in data tables.

SOURCE: 72 FR 60957, Oct. 26, 2007, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136 - 136y; 21 U.S.C. 346a.

Current through July1, 2022, 87 FR 39677. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 158. Data Requirements for Pesticides (Refs & Annos)
Subpart G. Ecological Effects

40 C.F.R. § 158.630

§ 158.630 Terrestrial and aquatic nontarget organisms data requirements table.

Effective: December 26, 2007
Currentness

(a) General. Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget data requirements for a particular pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) Use patterns.

(1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood use patterns. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for the general use patterns of forestry and residential outdoor use.

(3) In general, for all outdoor end-uses, including turf, the following studies are required: Two avian oral LD_{50}, two avian dietary LC_{50}, two avian reproduction studies, two freshwater fish LC_{50}, one freshwater invertebrate EC_{50}, one honeybee acute contact LD_{50}, one freshwater fish early-life stage, one freshwater invertebrate life cycle, and three estuarine acute LC_{50} /EC_{50} studies -- fish, mollusk and invertebrate. All other outdoor residential uses, i.e., gardens and ornamental will not usually require the freshwater fish early-life stage, the freshwater invertebrate life-cycle, and the acute estuarine tests.

(c) Key. R=Required; CR=Conditionally required; NR=Not required; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product; PAI=Pure active ingredient; EP=end-use product. Commas between the test substances (i.e., TGAI, TEP) indicate that data may be required on the TGAI or the TEP depending on the conditions set forth in the test note.

(d) Table. The following table shows the data requirements for nontarget terrestrial and aquatic organism. The table notes are shown in paragraph (e) of this section.

Terrestrial and Aquatic Nontarget Organism Data Requirements

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
	Avian and Mammalian Testing								
850.2100	Avian oral toxicity	R	R	R	R	CR	CR	TGAI	1, 2, 3
850.2200	Avian dietary toxicity	R	R	R	R	NR	NR	TGAI	1, 4
850.2400	Wild mammal toxicity	CR	CR	CR	CR	NR	NR	TGAI	5
850.2300	Avian reproduction	R	R	R	R	NR	NR	TGAI	1, 4
850.2500	Simulated or actual field testing	CR	CR	CR	CR	NR	NR	TEP	6, 7
	Aquatic Organisms Testing								
850.1075	Freshwater fish toxicity	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 8, 9, 26
850.1010	Acute toxicity freshwater invertebrates	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 9, 10, 26
850.1025	Acute toxicity estuarine and marine organisms	R	R	R	R	NR	NR	TGAI, TEP	1, 9, 11, 12, 26
	850.1035								
	850.1045								
	850.1055								
	850.1075								
850.1300	Aquatic invertebrate life cycle (freshwater)	R	R	R	R	NR	NR	TGAI	1, 10, 12
850.1350	Aquatic invertebrate life cycle (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 14, 15
850.1400	Fish early-life stage (freshwater)	R	R	R	R	NR	NR	TGAI	1, 12, 13
850.1400	Fish early-life stage (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 15, 16
850.1500	Fish life cycle	CR	CR	CR	CR	NR	NR	TGAI	17, 18
850.1710	Aquatic organisms bioavailability, biomagnification, toxicity	CR	CR	CR	CR	NR	NR	TGAI, PAI, degradate	19

850.1730									
850.1850									
850.1950	Simulated or actual field testing for aquatic organisms	CR	CR	CR	CR	NR	NR	TEP	7, 20
	Sediment Testing								
850.1735	Whole sediment: acute freshwater invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21
850.1740	Whole sediment: acute marine invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21, 23
	Whole sediment: chronic invertebrates freshwater and marine	CR	CR	CR	CR	NR	NR	TGAI	22, 23
	Insect Pollinator Testing								
850.3020	Honeybee acute contact toxicity	R	CR	R	R	NR	NR	TGAI	1
850.3030	Honey bee toxicity of residues on foliage	CR	CR	CR	CR	NR	NR	TEP	24
850.3040	Field testing for pollinators	CR	CR	CR	CR	NR	NR	TEP	25

(e) Test notes. The following test notes apply to terrestrial and aquatic nontarget organisms data requirements in the table to paragraph (d) of this section:

1. Data using the TGAI are required to support all outdoor end-use product uses including, but not limited to turf. Data are generally not required to support end-use products in the form of a gas, a highly volatile liquid, a highly reactive solid, or a highly corrosive material.

2. For greenhouse and indoor end-use products, data using the TGAI are required to support manufacturing-use products to be reformulated into these same end-use products or to support end-use products when there is no registered manufacturing-use product. Avian acute oral data are not required for liquid formulations for greenhouse and indoor uses. The study is not required if there is no potential for environmental exposure.

3. Data are required on one passerine species and either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. Data are preferred on waterfowl or upland game bird species for indoor and greenhouse uses.

4. Data are required on waterfowl and upland game bird species.

5. Tests are required based on the results of lower tier toxicology studies, such as the acute and subacute testing, intended use pattern, and environmental fate characteristics that indicate potential exposure.

6. Higher tier testing may be required for a specific use pattern when a refined risk assessment indicates a concern based on laboratory toxicity endpoints and refined exposure assessments.

7. Environmental chemistry methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory. Test standards and procedures for independent laboratory validation are available as addenda to the guideline for this test requirement.

8. Data are required on one coldwater fish and one warmwater fish for terrestrial, aquatic, forestry, and residential outdoor uses. For indoor and greenhouse uses, testing with only one of either fish species is required.

9. EP or TEP testing is required for any product which meets any of the following conditions:

i. The end-use pesticide will be introduced directly into an aquatic environment (e.g., aquatic herbicides and mosquito larvicides) when used as directed.

ii. The maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment is ≥ one-half the LC_{50} or EC_{50} of the TGAI when the EP is used as directed.

iii. An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

10. Data are required on one freshwater aquatic invertebrate species.

11. Data are required on one estuarine/marine mollusk, one estuarine/marine invertebrate and one estuarine/marine fish species.

12. Data are generally not required for outdoor residential uses, other than turf, unless data indicate that pesticide residues from the proposed use(s) can potentially enter waterways.

13. Data are required on one freshwater fish species. If the test species is different from the two species used for the freshwater fish acute toxicity tests, a 96–hour LC_{50} on that species must also be provided.

14. Data are required on one estuarine/marine invertebrate species.

15. Data are required on estuarine/marine species if the product meets any of the following conditions:

i. Intended for direct application to the estuarine or marine environment.

ii. Expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

iii. If the acute LC_{50} or EC_{50} < 1 milligram/liter (mg/l).

iv. If the estimated environmental concentration (EEC) in water is ≥ 0.01 of the acute EC_{50} or LC_{50} or if any of the following conditions exist:

A. Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.

B. Physicochemical properties indicate bioaccumulation of the pesticide.

C. The pesticide is persistent in water (e.g., half-life in water > 4 days).

16. Data are required on one estuarine/marine fish species.

17. Data are required on estuarine/marine species if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

18. Data are required on freshwater species if the end-use product is intended to be applied directly to water, or is expected to be transported to water from the intended use site, and when any of the following conditions apply:

i. If the estimated environmental concentration (EEC) is ≥0.1 of the no-observed-effect level in the fish early-life stage or invertebrate life cycle test;

ii. If studies of other organisms indicate that the reproductive physiology of fish may be affected.

19. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are < 1,000; or

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is < 5 days at pH 5, 7 and 9.

20. Data are required based on the results of lower tier studies such as acute and chronic aquatic organism testing, intended use pattern, and environmental fate characteristics that indicate significant potential exposure.

21. Data are required if:

i. The half-life of the pesticide in the sediment is ≤ 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

ii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

22. Data are required if:

i. The estimated environmental concentration (EEC) in sediment is > 0.1 of the acute LC_{50} /EC_{50} values and

ii. The half-life of the pesticide in the sediment is > 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

iii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

23. Sediment testing with estuarine/marine test species is required if the product is intended for direct application to the estuarine or marine environment or the product is expected to enter this environment in concentrations which the Agency believes to be significant, either by runoff or erosion, because of its expected use or mobility pattern.

24. Data are required only when the formulation contains one or more active ingredients having an acute LD_{50} of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.

25. Required if any of the following conditions are met:

i. Data from other sources (Experimental Use Permit program, university research, registrant submittals, etc.) indicate potential adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.);

ii. Data from residual toxicity studies indicate extended residual toxicity.

iii. Data derived from studies with terrestrial arthropods other than bees indicate potential chronic, reproductive or behavioral effects.

26. The freshwater fish test species for the TEP testing is the most sensitive of the species tested with the TGAI. Freshwater invertebrate and acute estuarine and marine organisms must also be tested with the EP or TEP using the same species tested with the TGAI.

SOURCE: 72 FR 60957, Oct. 26, 2007, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136 - 136y; 21 U.S.C. 346a.

Notes of Decisions (2)

Current through July1, 2022, 87 FR 39677. Some sections may be more current. See credits for details.

End of Document

50 C.F.R. § 402.01

§ 402.01 Scope.

Currentness

(a) This part interprets and implements sections 7(a)–(d) [16 U.S.C. 1536(a)–(d)] of the Endangered Species Act of 1973, as amended ("Act"). Section 7(a) grants authority to and imposes requirements upon Federal agencies regarding endangered or threatened species of fish, wildlife, or plants ("listed species") and habitat of such species that has been designated as critical ("critical habitat"). Section 7(a)(1) of the Act directs Federal agencies, in consultation with and with the assistance of the Secretary of the Interior or of Commerce, as appropriate, to utilize their authorities to further the purposes of the Act by carrying out conservation programs for listed species. Such affirmative conservation programs must comply with applicable permit requirements (50 CFR parts 17, 220, 222, and 227) for listed species and should be coordinated with the appropriate Secretary. Section 7(a)(2) of the Act requires every Federal agency, in consultation with and with the assistance of the Secretary, to insure that any action it authorizes, funds, or carries out, in the United States or upon the high seas, is not likely to jeopardize the continued existence of any listed species or results in the destruction or adverse modification of critical habitat. Section 7(a)(3) of the Act authorizes a prospective permit or license applicant to request the issuing Federal agency to enter into early consultation with the Service on a proposed action to determine whether such action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. Section 7(a)(4) of the Act requires Federal agencies to confer with the Secretary on any action that is likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat. Section 7(b) of the Act requires the Secretary, after the conclusion of early or formal consultation, to issue a written statement setting forth the Secretary's opinion detailing how the agency action affects listed species or critical habitat Biological assessments are required under section 7(c) of the Act if listed species or critical habitat may be present in the area affected by any major construction activity as defined in § 404.02. Section 7(d) of the Act prohibits Federal agencies and applicants from making any irreversible or irretrievable commitment of resources which has the effect of foreclosing the formulation or implementation of reasonable and prudent alternatives which would avoid jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat. Section 7(e)–(o)(1) of the Act provide procedures for granting exemptions from the requirements of section 7(a)(2). Regulations governing the submission of exemption applications are found at 50 CFR part 451, and regulations governing the exemption process are found at 50 CFR parts 450, 452, and 453.

(b) The U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) share responsibilities for administering the Act. The Lists of Endangered and Threatened Wildlife and Plants are found in 50 CFR 17.11 and 17.12 and the designated critical habitats are found in 50 CFR 17.95 and 17.96 and 50 CFR Part 226. Endangered or threatened species under the jurisdiction of the NMFS are located in 50 CFR 222.23(a) and 227.4. If the subject species is cited in 50 CFR 222.23(a) or 227.4, the Federal agency shall contact the NMFS. For all other listed species the Federal Agency shall contact the FWS.

SOURCE: 51 FR 19957, June 3, 1986, unless otherwise noted.

AUTHORITY: 16 U.S.C. 1531 et seq.

Notes of Decisions (311)

Current through July1, 2022, 87 FR 39677. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 50. Wildlife and Fisheries
Chapter IV. Joint Regulations (United States Fish and Wildlife Service, Department of the Interior and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce); Endangered Species Committee Regulations
Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart B. Consultation Procedures

50 C.F.R. § 402.14

§ 402.14 Formal consultation.

Effective: October 28, 2019
Currentness

(a) Requirement for formal consultation. Each Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat. If such a determination is made, formal consultation is required, except as noted in paragraph (b) of this section. The Director may request a Federal agency to enter into consultation if he identifies any action of that agency that may affect listed species or critical habitat and for which there has been no consultation. When such a request is made, the Director shall forward to the Federal agency a written explanation of the basis for the request.

(b) Exceptions.

(1) A Federal agency need not initiate formal consultation if, as a result of the preparation of a biological assessment under § 402.12 or as a result of informal consultation with the Service under § 402.13, the Federal agency determines, with the written concurrence of the Director, that the proposed action is not likely to adversely affect any listed species or critical habitat.

(2) A Federal agency need not initiate formal consultation if a preliminary biological opinion, issued after early consultation under § 402.11, is confirmed as the final biological opinion.

(c) Initiation of formal consultation.

(1) A written request to initiate formal consultation shall be submitted to the Director and shall include:

(i) A description of the proposed action, including any measures intended to avoid, minimize, or offset effects of the action. Consistent with the nature and scope of the proposed action, the description shall provide sufficient detail to assess the effects of the action on listed species and critical habitat, including:

(A) The purpose of the action;

(B) The duration and timing of the action;

(C) The location of the action;

(D) The specific components of the action and how they will be carried out;

(E) Maps, drawings, blueprints, or similar schematics of the action; and

(F) Any other available information related to the nature and scope of the proposed action relevant to its effects on listed species or designated critical habitat.

(ii) A map or description of all areas to be affected directly or indirectly by the Federal action, and not merely the immediate area involved in the action (i.e., the action area as defined at § 402.02).

(iii) Information obtained by or in the possession of the Federal agency and any applicant on the listed species and designated critical habitat in the action area (as required by paragraph (c)(1)(ii) of this section), including available information such as the presence, abundance, density, or periodic occurrence of listed species and the condition and location of the species' habitat, including any critical habitat.

(iv) A description of the effects of the action and an analysis of any cumulative effects.

(v) A summary of any relevant information provided by the applicant, if available.

(vi) Any other relevant available information on the effects of the proposed action on listed species or designated critical habitat, including any relevant reports such as environmental impact statements and environmental assessments.

(2) A Federal agency may submit existing documents prepared for the proposed action such as NEPA analyses or other reports in substitution for the initiation package outlined in this paragraph (c). However, any such substitution shall be accompanied by a written summary specifying the location of the information that satisfies the elements above in the submitted document(s).

(3) Formal consultation shall not be initiated by the Federal agency until any required biological assessment has been completed and submitted to the Director in accordance with § 402.12.

(4) Any request for formal consultation may encompass, subject to the approval of the Director, a number of similar individual actions within a given geographical area, a programmatic consultation, or a segment of a comprehensive plan. The provision in this paragraph (c)(4) does not relieve the Federal agency of the requirements for considering the effects of the action or actions as a whole.

(d) Responsibility to provide best scientific and commercial data available. The Federal agency requesting formal consultation shall provide the Service with the best scientific and commercial data available or which can be obtained during the consultation for an adequate review of the effects that an action may have upon listed species or critical habitat. This information may include the results of studies or surveys conducted by the Federal agency or the designated non-Federal representative. The Federal agency shall provide any applicant with the opportunity to submit information for consideration during the consultation.

(e) Duration and extension of formal consultation. Formal consultation concludes within 90 days after its initiation unless extended as provided below. If an applicant is not involved, the Service and the Federal agency may mutually agree to extend the consultation for a specific time period. If an applicant is involved, the Service and the Federal agency may mutually agree to extend the consultation provided that the Service submits to the applicant, before the close of the 90 days, a written statement setting forth:

(1) The reasons why a longer period is required,

(2) The information that is required to complete the consultation, and

(3) The estimated date on which the consultation will be completed.

A consultation involving an applicant cannot be extended for more than 60 days without the consent of the applicant. Within 45 days after concluding formal consultation, the Service shall deliver a biological opinion to the Federal agency and any applicant.

(f) Additional data. When the Service determines that additional data would provide a better information base from which to formulate a biological opinion, the Director may request an extension of formal consultation and request that the Federal agency obtain additional data to determine how or to what extent the action may affect listed species or critical habitat. If formal consultation is extended by mutual agreement according to § 402.14(e), the Federal agency shall obtain, to the extent practicable, that data which can be developed within the scope of the extension. The responsibility for conducting and funding any studies belongs to the Federal agency and the applicant, not the Service. The Service's request for additional data is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act. If no extension of formal consultation is agreed to, the Director will issue a biological opinion using the best scientific and commercial data available.

(g) Service responsibilities. Service responsibilities during formal consultation are as follows:

(1) Review all relevant information provided by the Federal agency or otherwise available. Such review may include an on-site inspection of the action area with representatives of the Federal agency and the applicant.

(2) Evaluate the current status and environmental baseline of the listed species or critical habitat.

(3) Evaluate the effects of the action and cumulative effects on the listed species or critical habitat.

(4) Add the effects of the action and cumulative effects to the environmental baseline and in light of the status of the species and critical habitat, formulate the Service's opinion as to whether the action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

(5) Discuss with the Federal agency and any applicant the Service's review and evaluation conducted under paragraphs (g)(1)–(3) of this section, the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant can take to avoid violation of section 7(a)(2). The Service will utilize the expertise of the Federal agency and any applicant in identifying these alternatives. If requested, the Service shall make available to the Federal agency the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The 45–day period in which the biological opinion must be delivered will not be suspended unless the Federal agency secures the written consent of the applicant to an extension to a specific date. The applicant may request a copy of the draft opinion from the Federal agency. All comments on the draft biological opinion must be submitted to the Service through the Federal agency, although the applicant may send a copy of its comments directly to the Service. The Service will not issue its biological opinion prior to the 45–day or extended deadline while the draft is under review by the Federal agency. However, if the Federal agency submits comments to the Service regarding the draft biological opinion within 10 days of the deadline for issuing the opinion, the Service is entitled to an automatic 10–day extension on the deadline.

(6) Formulate discretionary conservation recommendations, if any, which will assist the Federal agency in reducing or eliminating the impacts that its proposed action may have on listed species or critical habitat.

(7) Formulate a statement concerning incidental take, if such take is reasonably certain to occur.

(8) In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data available and will give appropriate consideration to any beneficial actions as proposed or taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation. Measures included in the proposed action or a reasonable and prudent alternative that are intended to avoid, minimize, or offset the effects of an action are considered like other portions of the action and do not require any additional demonstration of binding plans.

(h) Biological opinions.

(1) The biological opinion shall include:

(i) A summary of the information on which the opinion is based;

(ii) A detailed discussion of the environmental baseline of the listed species and critical habitat;

(iii) A detailed discussion of the effects of the action on listed species or critical habitat; and

(iv) The Service's opinion on whether the action is:

(A) Likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy" biological opinion); or

(B) Not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion).

(2) A "jeopardy" biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, the Service will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

(3) The Service may adopt all or part of:

(i) A Federal agency's initiation package; or

(ii) The Service's analysis required to issue a permit under section 10(a) of the Act in its biological opinion.

(4) A Federal agency and the Service may agree to follow an optional collaborative process that would further the ability of the Service to adopt the information and analysis provided by the Federal agency during consultation in the development of the Service's biological opinion to improve efficiency in the consultation process and reduce duplicative efforts. The Federal agency and the Service shall consider the nature, size, and scope of the action or its anticipated effects on listed species or critical habitat, and other relevant factors to determine whether an action or a class of actions is appropriate for this process. The Federal agency and the Service may develop coordination procedures that would facilitate adoption of the initiation package with any necessary supplementary analyses and incidental take statement to be added by the Service, if appropriate, as the Service's biological opinion in fulfillment of section 7(b) of the Act.

(i) Incidental take.

(1) In those cases where the Service concludes that an action (or the implementation of any reasonable and prudent alternatives) and the resultant incidental take of listed species will not violate section 7(a)(2), and, in the case of marine mammals, where the taking is authorized pursuant to section 101(a)(5) of the Marine Mammal Protection Act of 1972, the Service will provide with the biological opinion a statement concerning incidental take that:

(i) Specifies the impact, i.e., the amount or extent, of such incidental taking on the species (A surrogate (e.g., similarly affected species or habitat or ecological conditions) may be used to express the amount or extent of anticipated take provided that the biological opinion or incidental take statement: Describes the causal link between the surrogate and take of the listed species, explains why it is not practical to express the amount or extent of anticipated take or to monitor take-related impacts in terms of individuals of the listed species, and sets a clear standard for determining when the level of anticipated take has been exceeded.);

(ii) Specifies those reasonable and prudent measures that the Director considers necessary or appropriate to minimize such impact;

(iii) In the case of marine mammals, specifies those measures that are necessary to comply with section 101(a)(5) of the Marine Mammal Protection Act of 1972 and applicable regulations with regard to such taking;

(iv) Sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or any applicant to implement the measures specified under paragraphs (i)(1)(ii) and (i)(1)(iii) of this section; and

(v) Specifies the procedures to be used to handle or dispose of any individuals of a species actually taken.

(2) Reasonable and prudent measures, along with the terms and conditions that implement them, cannot alter the basic design, location, scope, duration, or timing of the action and may involve only minor changes.

(3) In order to monitor the impacts of incidental take, the Federal agency or any applicant must report the progress of the action and its impact on the species to the Service as specified in the incidental take statement. The reporting requirements will be established in accordance with 50 CFR 13.45 and 18.27 for FWS and 50 CFR 216.105 and 222.301(h) for NMFS.

(4) If during the course of the action the amount or extent of incidental taking, as specified under paragraph (i)(1)(i) of this Section, is exceeded, the Federal agency must reinitiate consultation immediately.

(5) Any taking which is subject to a statement as specified in paragraph (i)(1) of this section and which is in compliance with the terms and conditions of that statement is not a prohibited taking under the Act, and no other authorization or permit under the Act is required.

(6) For a framework programmatic action, an incidental take statement is not required at the programmatic level; any incidental take resulting from any action subsequently authorized, funded, or carried out under the program will be addressed in subsequent section 7 consultation, as appropriate. For a mixed programmatic action, an incidental take statement is required at the programmatic level only for those program actions that are reasonably certain to cause take and are not subject to further section 7 consultation.

(j) Conservation recommendations. The Service may provide with the biological opinion a statement containing discretionary conservation recommendations. Conservation recommendations are advisory and are not intended to carry any binding legal force.

(k) Incremental steps. When the action is authorized by a statute that allows the agency to take incremental steps toward the completion of the action, the Service shall, if requested by the Federal agency, issue a biological opinion on the incremental step being considered, including its views on the entire action. Upon the issuance of such a biological opinion, the Federal agency may proceed with or authorize the incremental steps of the action if:

(1) The biological opinion does not conclude that the incremental step would violate section 7(a)(2);

(2) The Federal agency continues consultation with respect to the entire action and obtains biological opinions, as required, for each incremental step;

(3) The Federal agency fulfills its continuing obligation to obtain sufficient data upon which to base the final biological opinion on the entire action;

(4) The incremental step does not violate section 7(d) of the Act concerning irreversible or irretrievable commitment of resources; and

(5) There is a reasonable likelihood that the entire action will not violate section 7(a)(2) of the Act.

(l) Expedited consultations. Expedited consultation is an optional formal consultation process that a Federal agency and the Service may enter into upon mutual agreement. To determine whether an action or a class of actions is appropriate for this type of consultation, the Federal agency and the Service shall consider the nature, size, and scope of the action or its anticipated effects on listed species or critical habitat and other relevant factors. Conservation actions whose primary purpose is to have beneficial effects on listed species will likely be considered appropriate for expedited consultation.

(1) Expedited timelines. Upon agreement to use this expedited consultation process, the Federal agency and the Service shall establish the expedited timelines for the completion of this consultation process.

(2) Federal agency responsibilities. To request initiation of expedited consultation, the Federal agency shall provide all the information required to initiate consultation under paragraph (c) of this section. To maximize efficiency and ensure that it develops the appropriate level of information, the Federal agency is encouraged to develop its initiation package in coordination with the Service.

(3) Service responsibilities. In addition to the Service's responsibilities under the provisions of this section, the Service will:

(i) Provide relevant species information to the Federal agency and guidance to assist the Federal agency in completing its effects analysis in the initiation package; and

(ii) Conclude the consultation and issue a biological opinion within the agreed-upon timeframes.

(m) Termination of consultation.

(1) Formal consultation is terminated with the issuance of the biological opinion.

(2) If during any stage of consultation a Federal agency determines that its proposed action is not likely to occur, the consultation may be terminated by written notice to the Service.

(3) If during any stage of consultation a Federal agency determines, with the concurrence of the Director, that its proposed action is not likely to adversely affect any listed species or critical habitat, the consultation is terminated.

Credits

[54 FR 40350, Sept. 29, 1989; 73 FR 76287, Dec. 16, 2008; 74 FR 20423, May 4, 2009; 80 FR 26844, May 11, 2015; 84 FR 45016, Aug. 27, 2019; 84 FR 50333, Sept. 25, 2019]

SOURCE: 51 FR 19957, June 3, 1986, unless otherwise noted.

AUTHORITY: 16 U.S.C. 1531 et seq.

Notes of Decisions (319)

Current through July1, 2022, 87 FR 39677. Some sections may be more current. See credits for details.

End of Document

ADDENDUM OF STANDING DECLARATIONS

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF DR. LASZLO MADARAS

I, Dr. Laszlo Madaras, do hereby affirm and state:

1. I am a Board Certified family physician and Migrant Clinicians Network's Chief Medical Officer. I have practiced family medicine for 25 years. I have worked with farmworkers since the mid-1980s, when I assisted agricultural fisheries workers in the Congo as regional fisheries coordinator with the U.S. Peace Corps.

2. In 1993, I earned an MD and Masters in Public Health from Tufts University School of Medicine. My experience with vulnerable

medical populations includes my medical practice with the American Refugee Committee on the Congo-Rwandan border during the 1994 Rwandan genocide, as well as my practice on the border of Hungary and the former Yugoslavia in 1995.

3. For more than two decades, I have worked in inpatient and outpatient medicine in Pediatrics, Adult Medicine, and Obstetrics at the Keystone Health Center in Chambersburg, Pennsylvania. My practice includes the regular treatment of farmworkers. From 2001 to 2005, I was the Assistant Medical Director of the Keystone Community Health Center. I have also worked as a staff physician in Tuberculosis control with the Pennsylvania State Health Department since 2012.

4. In addition to my position with the Keystone Health Center, I teach hospital medicine to Penn State nurse practitioner and physician assistant (PA) students and medical residents. I was named a Fellow of the American Academy of Family Physicians in 2020.

5. Migrant Clinicians Network is a 501(c)(3) nonprofit organization that works to serve doctors and patients on the move. This

includes patients who are farmworkers, day laborers, migrants, and refugees — populations that have made the choice to migrate or have been forcibly displaced. Migrant Clinicians Network's mission is to provide practical solutions on issues where vulnerability, migration, and health intersect, and to promote and ensure the health of vulnerable populations.

6. Migrant Clinicians Network was established in 1984. One of the organization's initial efforts to help clinicians in treating migrants for diseases like Tuberculosis, a deadly illness that killed thousands daily across the globe. Tuberculosis required six months of antibiotic treatment, including streptomycin. Migrants with Tuberculosis who travelled back and forth between Mexico and Texas experienced great difficulty in getting continuous, consistent antibiotic treatment. Migrant Clinicians Network created an initiative to help transmit health records and facilitate information flows between health clinics in Mexico and Texas so that those patients could receive ongoing, appropriate, and effective care.

7. Since its founding, Migrant Clinicians Network has supported clinicians who serve migrants moving to and across the U.S. in tandem

with the fruit picking seasons. The organization offers technical assistance, professional development, and coordination to physicians and other healthcare providers in community health centers and in other healthcare settings.

8. The organization works to connect patients on the move with clinicians in our network and helps to facilitate the transfer of critical patient information and records from clinic to clinic. It offers virtual case management directly to patients through an organizational program called Health Network. We offer our services to any mobile patients who cannot continue a necessary medical treatment plan with a prior healthcare provider. We assist in the enrollment of mobile patients in the next receiving clinic. We also work to provide pre-natal care to migrant women who are in their third trimester of pregnancy and need urgent assistance.

9. Migrant Clinicians Network also engages in extensive medical education efforts around a variety of health and safety matters — both for clinicians and for farmworkers. We regularly host online seminars and learning collaboratives. And we also provide on-the-ground trainings to

farmworkers and clinicians, develop medical education resources for both doctors and patients, and conduct advocacy to improve healthcare and health outcomes for vulnerable patient populations.

10. Migrant Clinicians Network has nine members of its Board of Directors and more than 10,000 members of its constituent network. We have a professional staff of about 40 people spread across offices in various states in the mainland U.S. — including California — and in Puerto Rico.

11. To carry out our farmworker and pesticides education goals, we train community health workers who are bilingual and can communicate and work directly with migrant farmworkers. MCN staff members publish materials and go out into the field to conduct trainings with community health workers who promote pesticide safety among farmworkers. For example, farms are often non-compliant with personal protective equipment ("PPE") requirements, so education and advocacy are necessary to boost farmworkers' knowledge about PPE and to improve compliance.

12. Almost every member of our farmworker education group has

some Spanish fluency. We also have IT, editorial and technical staff who assist in creating presentations, publications, and webinars and in designing and developing the organization's website. These elements of our work are essential to disseminating educational information to farmworkers and clinicians. We pull staff from all parts of Migrant Clinicians Network to meet our educational commitments to farmworkers as they arise.

13. Migrant Clinicians Network also publishes a quarterly newsletter and hosts a blog site. These forums provide vehicles for publishing important medical and educational information for clinicians and patients. We have published numerous pesticide-related comic books in Spanish that illuminate the health threats associated with pesticide exposure. We are constantly trying to innovate new and accessible ways of reaching the vulnerable migrant populations that we serve.

14. Migrant Clinicians Network's Board of Directors comprise frontline clinicians, policymakers, researchers, and academics who lend their expertise to the organization, shape the organization's direction,

exercise voting rights over the organization's financial and budgetary matters, contribute to organizational fundraising efforts, and develop new organizational projects and initiatives. Board Members who are clinicians working in the medical trenches provide critical insight into the organization's direction.

15. Board Members contribute financial donations to the organization and engage in fundraising efforts for the organization. Board Members also exercise voting rights over matters related to the organization's budget and financial resources.

16. Often, Migrant Clinicians Network's executive leadership send out emails to Board Members to solicit Board Member input on strategic issues and on decisions as to whether to undertake a project or advocacy effort. In the past, such emails have, for example, sought input from Board Members on whether Migrant Clinicians Network should move forward with a certain grant application, or proceed with a partnership effort with an aligned organization.

17. Our Board Members are also instrumental in pushing Migrant

Clinicians Network to engage in specific activities and issues as part of our advocacy. For instance, our Board Members urged the organization to move forward swiftly with research, training and mobilization efforts around the COVID-19 pandemic. Based on some of their own experiences in clinical settings, Board Members guided Migrant Clinicians Network to provide instruction and organize farmworkers and farms to set up COVID-19 testing infrastructure that would allow farmworkers with pending tests and farmworkers with positive tests to isolate from other workers to prevent the spread of disease. Very early on in the pandemic, Board Members encouraged the organization to host a webinar presenting information to clinicians and patients showing that aerosols were likely a major route of COVID-19 transmission. We acted ahead of the U.S. Centers for Diseases Control and Prevention and other major health organizations in the U.S. to put out and publicize that information.

18. Board Members and members of our constituent network also play a key role in influencing Migrant Clinicians Network's advocacy pushing for federal and state bans on chlorpyrifos, a dangerous and

neurotoxic pesticide. Across changes in federal administrations, our Board Members and constituents insisted that we keep putting out materials and engaging with policymakers to compel the federal government to protect the public from exposure to chlorpyrifos.

19. Members of Migrant Clinicians Network's constituent network are also critical in making the organization aware of the need to work in specific communities and geographic areas in America. When physicians report incidents of pesticide poisonings, we can identify patterns in particular parts of the country and marshal our resources to investigate and respond to potential health emergencies.

20. Migrant Clinicians Network opted to get involved in this case because EPA's decision to expand the use of streptomycin in citrus crops undermines our mission to protect the health of farmworkers, migrants, and other vulnerable populations. Clinicians in our constituent network tell us that they are worried about pesticides in general and antibiotics used as pesticides specifically. In medicine, the control of antibiotic dosage is and should be incredibly precise. In many hospitals, administration of

antibiotics is carefully managed by an antibiotic stewardship committee. Doctors will set the antibiotic dosage very carefully, based on a person's weight, bodily functions, and other factors. But when antibiotics are sprayed on citrus crops, that action effectively represents an uncontrolled release of antibiotics into the environment. There's no telling what dosage of the antibiotic individuals and farmworkers will be exposed to. The prospect of the release of enormous quantities of streptomycin into the environment is of tremendous concern to the clinicians that we work with.

21. If EPA's dangerous decision is allowed to stand, Migrant Clinicians Network will be forced to divert significant resources to educate about, and protect against, increasing exposure to streptomycin and antibiotic resistant bacteria. Many of our constituent members are farmworkers, including a substantial number in Florida and California. The widespread use of streptomycin on citrus groves will result in more requests from farmworkers for case management assistance from Migrant Clinicians Network. We will have to devote substantially more time and resources responding to and helping patients who have either suffered

streptomycin poisoning or have been exposed to an antibiotic resistant disease resulting from the increased and indiscriminate use of streptomycin on agricultural crops.

22. Migrant Clinicians Network will also be forced to disseminate targeted educational materials and engage in increased on-the-ground educational efforts as a result of EPA's permitted expansion of streptomycin use. This includes, for example, information on identifying symptoms of acute toxicity from direct exposure to streptomycin. In addition, we will also spend time and resources tracking, publishing, and publicizing the latest research about the dangers posed by the growth of antibiotic resistant bacteria and the rate of increase of streptomycin-resistance in patient populations.

23. In addition to harming Migrant Clinician Network's mission by diverting time and resources away from other pressing medical issues to educating about, and protecting against, exposure to streptomycin and antibiotic resistant bacteria, EPA's decision will also injure Board Members and members of our constituent network because direct exposure to

streptomycin can cause harmful toxicity.

24. Board Members and members of our constituent network that are physicians will now face circumstances where a patient presents certain symptoms such as vomiting or hearing loss, and they will be forced to treat the patient for a potential streptomycin overdose. These Board Member and constituent physicians risk direct exposure to streptomycin through dermal contact with the pesticide.

25. Farmworkers and other migrants in our constituent network may also be exposed to toxic levels of streptomycin and suffer severe health harms as a result.

26. Board Members and members of our constituent network will additionally be harmed by the spread of antibiotic resistant diseases because of the massive expansion of agricultural streptomycin use. Members who are physicians will face increased exposure to antibiotic resistant diseases in their practice and will suffer adverse health impacts as a result of that exposure. Physicians, farmworkers, and other migrants in our constituent network will also be exposed to antibiotic resistant diseases

that would otherwise not exist or be as virulent but for EPA's dangerous action. Board Member and constituent physicians will be forced to spend more time and dedicate new resources to combatting streptomycin resistant diseases in their patient populations.

27. Given the very real risk of experiencing and attending to severe and preventable physical health harms related to increased exposure to streptomycin and antibiotic resistant bacteria, Board Members and members of our constituent network will experience anxiety and emotional distress as a result of EPA's decision to permit widespread streptomycin use on citrus crops.

28. If EPA were to reverse its approval of widespread use of streptomycin on crops, Migrant Clinicians Network would not need to deploy its resources to assist and educate constituent members and other physicians and farmworkers on streptomycin exposure and the spread of streptomycin-resistant diseases. Migrant Clinicians Network's Board Members and constituents would also not risk suffering severe, undue physical and emotional health harms. For our patients and doctors,

removing streptomycin from agricultural use will allow for a safer environment.

29. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

SIGNED: December 17, 2021.

Dr. Laszlo Madaras

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF EVA GALVEZ

I, Dr. Eva Galvez, do hereby affirm and state:

1. I am an active member of the Board of Directors of Migrant Clinicians Network and a former Board Chair. I am a Board-Certified family physician. I have practiced medicine for more than 15 years, and I work in a federally qualified community health clinic in Hillsboro, Oregon, with a large number of farmworker patients.

2. Migrant Clinician Network's mission is to assist migrant populations, to support farmworker communities, and to promote public health more broadly.

3. Migrant Clinician Network's Board provides oversight to the organization's Chief Executive Officer (CEO), helps to ensure the organization's financial sustainability, and influences the organization's decisions to take on certain projects or engage in specific types of advocacy and activities. The Board also helps to steer the organization's course, ensuring that Migrant Clinicians Network stays true to its mission. My responsibilities include leading a monthly executive team meeting which includes Migrant Clinician Network's CEO and Chief Financial Officer.

4. Migrant Clinicians Network's Board members additionally give support to different projects or areas within the organization. For example, I support much of the organization's Spanish-speaking outreach and education. This has afforded me the opportunity to work directly with many of Migrant Clinician Network's staff.

5. As a Board Member, I and my fellow Board Members influence Migrant Clinician Network's advocacy in multiple crucial ways. Migrant Clinicians Network is very nimble and pivots quickly, so the organization is always on the front lines of emerging health issues. Board Members often play a role in redirecting the organization's resources to address novel and emergent health issues. COVID-19 is just one example of this. Migrant Clinician Network's Board Members were instrumental in pressing the organization to provide community and clinical education about COVID-19 as early as March 2020. Board Members ensured that the organization provided information to its network on how COVID-19 is transmitted, and how such transmission can be prevented or mitigated. I was directly involved with many of those webinars and have continued to press for and to be involved in Migrant Clinicians Network's provision of resources and education on COVID-19 to clinicians.

6. Our wider network of member constituents, which consists of doctors and patients specially connected with Migrant Clinicians Network, also influences our work in important ways. For instance, Migrant

Clinicians Network's extensive work responding to pandemics such as Zika and SARS was driven by the requests and expressed concerns of its member clinicians. Migrant Clinicians Network is always listening to its members to learn about what is happening on the ground. When a member clinician says, "we're hearing about Zika percolating up from Brazil, and we have at-risk patients travelling to the U.S. from Mexico," requesting guidance from Migrant Clinicians Network, the organization will respond with resources and education. Migrant Clinicians Network is there to provide support to clinicians on the front lines, as well as to patients.

7. In addition to being the Board Chair of Migrant Clinicians Network, I have also been part of the organization's larger member network for more than fifteen years. I first joined the organization's network in 2005 during my second year of medical residency, after learning about the organization at a conference. I recall hearing about Migrant Clinicians Network's compelling work, and immediately knowing that this was an organization that I wanted to be a part of and contribute to. I first started attending Migrant Clinicians Network's seminars and

using their educational resources, which I have found – and continue to find – to be invaluable. As a member of the network, I have also referred numerous patients to Migrant Clinicians Network, enlisting the organization's assistance and labor in connecting patients to new clinics closer to their destination locations and in supporting the resulting transition in medical care when my patients move across the country. Because of my membership in the organization's network, I became connected to senior staff members at Migrant Clinicians Network, and eventually joined the Board.

8. The mission of Migrant Clinicians Network is something that I'm extremely passionate about. It is deeply connected to my upbringing and my background. I am the daughter of a Mexican immigrant. Both of my parents were seasonal and migrant farmworkers. I grew up having a unique perspective of the challenges that migrant and seasonal farmworkers face, particularly when it comes to poor health outcomes. I wanted to do something with my life to bring better opportunities and better health outcomes to these farmworker communities who were

foundational in my early life experiences and with whom I share a profound sense of kinship. When deciding upon my career path, I felt that healthcare was the best way to serve farmworker communities— indeed, that drive to serve farmworker communities propelled my initial decision to go into family medicine. Throughout my career, I have always worked with a keen sense of mission and a powerful passion to help farmworker groups and other marginalized communities, especially those that experience barriers to access to healthcare. I feel that Migrant Clinicians Network perfectly complements my vision, since it is an organization that is working towards a mission of improving health for farmworkers, for migrants, for marginalized communities, and, ultimately, for everybody.

9. Because of my family's history working as farm laborers and because I care so deeply about my patients, my work with Migrant Clinicians Network is very personal to me. My role as Migrant Clinicians Network's Board Chair is more than just a volunteer position — it is central to my identity and life purpose.

10. Being involved in this case to admonish EPA to do its job to protect farmworkers and the public from health harms caused by the inappropriate agricultural use of streptomycin goes right to the mission of Migrant Clinicians Network. At Migrant Clinicians Network, we are continuously striving to improve the health of migrants and other vulnerable populations. These are populations that face formidable barriers to achieving good health. We know that migrants and seasonal workers grapple with a tremendous number of hazards when they are at work, and that these hazards present substantially increased health risks relative to the general population.

11. I am deeply concerned about the harm that EPA's dangerous decision to expand the permitted use of streptomycin will cause to my patients' communities. About 30 percent of the patients served by my medical clinic are farmworkers, including migrant and seasonal farmworkers. I also visit farmworker labor camps each year from May to August in the summer to provide farmworkers with basic medical services, preventative care, health screenings, and education.

12. Most of my patients also belong to communities with a substantial farmworker presence or have other family members who are farmworkers. Although I work in Oregon, many of my farmworker patients are seasonal farmworkers, who travel across America picking fresh fruit for the country. Some of my patients move downstream from the citrus groves in California to the berry and apple orchards in Oregon. These farmworkers also have family members who are making similar trips across the country — some of them work in citrus groves in Florida during part of the year. As a result, some of my farmworker patients will be exposed to streptomycin and to more, and more virulent, antibiotic resistant diseases because of EPA's registration of streptomycin for use on citrus crops.

13. EPA's recent approval of the use of massive volumes of streptomycin for agriculture weighs heavily on my mind and causes me great worry. My farmworker patients tend to work in crowded conditions. Those congested conditions also extend to my patients' home life, whether because they are forced to live in labor camps or because they are paid such

low wages that they can't afford to live in separate housing units. In farmworker communities, many families live in shared apartments or houses. A substantial number of farmworker families also reside in labor camps, which are notoriously squalid. For example, during my annual visits to farmworker labor camps, I have witnessed ten or more people living in the same small cabin, cohabitating in unsanitary conditions that you could not imagine occurring or being tolerated in this country.

14. These kinds of dense, degrading, and cramped conditions give rise to higher rates of infectious diseases and infectious disease transmission. The infectious diseases disproportionately afflicting farmworker communities range from everyday common colds to the pernicious, powerful kinds of antibiotic resistant diseases that result from the overuse of antibiotics like streptomycin. For instance, I am keenly aware that methicillin-resistant Staphylococcus aureus (MRSA), a cause of staph infection, can spread rapidly in farmworker communities and its spread has been shown to be linked to the overuse of antibiotics in

agriculture. I worry that this will be the pattern that is followed by the improperly expanded use of streptomycin on farms.

15. Antibiotic resistant diseases are rapidly passed along among family members and communities like a chain reaction. A person directly exposed to streptomycin sprayed on citrus crops represents just the tip of the iceberg in terms of the harm caused. I am very concerned that, as a result of EPA's streptomycin registration, patients who have contracted antibiotic resistant diseases in citrus groves in California or Florida could travel to Oregon and spread those diseases among the patient population that I treat.

16. My patients are particularly vulnerable to antibiotic resistant diseases. They are mostly Spanish speaking, first generation, and immigrant. The overwhelming majority of farmworkers I care for do not have health insurance. My patients do have some access to healthcare because of community health centers like mine. But even with our clinic, my patients face high barriers to accessing adequate healthcare on a day-to-day basis. Many live very far from my clinic and reside in public transit

deserts. My patients also face significant cultural and language barriers to accessing healthcare. Fear and intimidation pervade farmworkers' sentiments towards the medical legal system, particularly given concerns around revealing documentation status.

17. Pesticides such as streptomycin enter the body in myriad different ways. Pesticides can enter through the mouth, through the skin, and through mucus membranes. Pesticides also transfer very easily. If, having been exposed to a pesticide, you sit in your car and your child then sits in that same spot, your child will be exposed to that pesticide. Because pesticides stay on surfaces, I really worry about children of farmworkers – especially as a former child of farmworkers myself – who are wandering outside and playing on playground equipment and grass with transferrable streptomycin residue. These kids are ingesting a much greater volume of the chemical compared to their body mass than the average adult.

18. Physicians like me who treat entire farmworker families and farmworker communities are compelled to grapple with the family and

community-level adverse health impacts of streptomycin and other pesticide and toxic chemicals. This is a heavy burden.

19. I fear that my patients and their families will get sick and die as a result of EPA's approval of expanded streptomycin use on crops. I especially fear for my many patients who are pregnant farmworkers because I am aware that streptomycin and streptomycin-resistant diseases can cause potent fetal harm. Thinking about my patients suffering or dying because of EPA's action to allow farms to large amounts of streptomycin causes me emotional distress.

20. I also fear that I will face increased exposure to antibiotic-resistant diseases because I am in regular contact with farmworker communities, including members of such communities who have travelled to, worked on, or lived near citrus groves in California, Florida, and elsewhere.

21. I anticipate spending more time treating patients for streptomycin-resistant diseases if EPA's approval continues without adjustment. These resilient diseases will linger in my patients' bodies for

longer. I expect that I will be forced to dedicate time and resources to researching alternative medical treatments effective to cure streptomycin-resistant diseases. I also expect to spend more time and exert greater efforts to counsel and help patients to access healthcare because of their increased exposure to antibiotic resistant diseases.

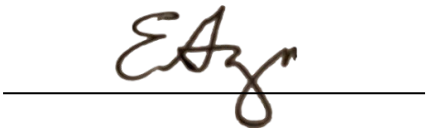
22. From my experience, the personal protective equipment used by farmworkers (PPE) is absolutely inadequate to prevent antibiotic-resistant disease and pesticide transfer. We know that pesticide residue remains in the air and on surfaces for a very long time after it is initially sprayed. Although workers spraying pesticides do sometimes wear protective gear, the farmworkers who subsequently go out into the fields to pick, plant, and tend to the fruits do not wear that kind of PPE. These farmworkers may wear hats and gloves, but many do not even take those basic precautions because gloves can hinder their ability to work quickly with their hands and meet the intensely demanding requirements imposed on them by their employers.

23. If a court orders EPA to reverse its approval of streptomycin, the time and labor that I put into treating and preventing antibiotic resistant diseases among my patients will be lessened. Such a court decision would reduce the risk of death and illness from streptomycin resistant infections among my patients, and would substantially ease my mind, quieting my distress. It would be a step in the right direction for health equity for me and for my patients, the people who are working to ensure that all Americans have food on our tables.

24. If a court were to compel EPA to conduct a more rigorous review of the health risks and benefits of streptomycin, that would ease my mind as well. I am deeply concerned that the benefits of streptomycin use on crops were overstated. My patients and I would be benefited by better and more clear information about the impacts of streptomycin exposure on their health. I would have to undertake less of my own personal research to provide that information to patients and to colleagues.

25. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

SIGNED: February 16, 2022, in Hillsboro, Oregon.



Dr. Eva Galvez

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF JAY FELDMAN

I, Jay Feldman, do hereby affirm and state:

1. I am the Executive Director of Beyond Pesticides, a nonprofit membership association that serves a nationwide network of individuals and groups working to increase the safe use of pesticides and reduce or end the use of dangerous chemicals.

2. I have a Masters from Virginia Polytechnic Institute and State University in urban and regional planning, with an emphasis on public health. I am a cofounder of Beyond Pesticides and have served as its

Director since 1981. As Director, I work to educate the public, organizations, and officials on the safe use of pesticides, the need to increase protections against toxic pesticides, and alternatives to pesticides.

3. Beyond Pesticides is based in Washington, D.C. and has over 1,000 organizational and individual members in California, Florida, Texas, Arizona, and other states. Beyond Pesticides advocates on behalf of farmworkers, individuals, communities, fish and wildlife, and other aspects of the environment exposed to pesticides.

4. Our mission is to educate the public and decision-makers on the hazards of pesticides – including antibiotics – and alternatives to pesticide use. Nationally and in state capitals, Beyond Pesticides works on behalf of its members to inform the public and decision-makers about the adverse impacts of pesticides, and to influence regulatory and legislative decisions on pesticide use.

5. Beyond Pesticides is a science-based organization that works at the intersection of policy and advocacy. Beyond Pesticides manages a series of databases that track the scientific literature, incidence of pesticide-

induced disease, and regulatory processes related to pesticide use, management, and exposure. We continually update Beyond Pesticides' Gateway on Pesticides Hazards and Safe Pest Management database to help ensure the public's understanding of the potential hazards of pesticides and alternatives so people can make informed choices and have sufficient information to voice their positions on government policies at the local, state, federal, and international levels of governance.

6. Beyond Pesticides also hosts an annual national conference that brings together scientists, policymakers, legal experts, practitioners, our membership, and the general public. Our most recent conference – the 38th National Pesticide Forum – offered talks and workshops on farmworker poisonings, the medical community's response to pesticide poisonings, and the latest research on the health effects of pesticides. The annual National Pesticide Forum that we host routinely includes workshops and plenary sessions on the regulatory and statutory policies governing the use of pesticides.

7. Dues-paying members of Beyond Pesticides inform issues of importance to the organization and shape its advocacy efforts. We regularly recommend an "Action of the Week" that our members can take to advocate against pesticides policies that are harmful to the environment and public and worker health. Our members tend to be very engaged with the science and the policy around pesticides and in communicating with policymakers. We solicit our membership's opinion on key issues through our website and maintain open channels of communication with our members on social media. Our annual conference is also a forum for Beyond Pesticides' members to convey priorities and feedback to the organization's leadership.

8. Beyond Pesticides also maintains an open phone line through which members communicate with the organization and influence its priorities. Through our phone line, we hear from several members each day — and from dozens of members each week – who share their concerns, and ask questions about pesticide use in their communities, pesticide drift and its impact, and what choices to make in the marketplace to be safe. We

have many members who live in agricultural areas and express concerns about pesticides sprayed on crops by agricultural producers. Members with various illnesses, including cancers and other diseases, often call Beyond Pesticides to ask about the link between pesticide exposure and their health conditions.

9. We regularly publish a variety of educational materials related to pesticides, including antibiotics. For the last 20 years, Beyond Pesticides has produced a nationally distributed, quarterly publication that discusses farmworker poisonings, alternatives to pesticides use, regulatory decisions regarding the risks and benefits of pesticide use, and organic farming. Each day, Beyond Pesticides publishes a Daily News blog which tracks the latest news on policy and science and local, state, and federal action on pesticides. Beyond Pesticides additionally conducts research and produces reports on the use of and alternatives to dangerous pesticides.

10. Beyond Pesticides' advocacy against the use and misuse of streptomycin in agriculture is rooted in my own experience as an Obama administration appointee on the National Organic Standards Board from

2009-2016. During my tenure on the National Organic Standards Board, in 2014, we banned the use of streptomycin on organic crops. Through that process, I became very familiar with the serious health harms stemming from the use of streptomycin in agriculture. To implement the prohibition of use of streptomycin on organic crops, the Board needed to be educated by Society of Infectious Disease doctors on the issue of horizontal gene transfer — the transfer of antibiotic resistance genes among different bacterial species. This, in Beyond Pesticides' view, is one of the central problems with agricultural application of antibiotics. The problem with the use of streptomycin in agriculture is not just with the harmful impacts from ingestion. The problem is also that these antibiotics are released into, and move through, the environment and have an ongoing deleterious effect on human health because of the rapid spread and growth of antibiotic resistant bacteria.

11. Beyond Pesticides has taken a very strong position against the agricultural use of streptomycin because of the existential public health threat that such use represents. Beyond Pesticides submitted comments to

the U.S. Environmental Protection Agency in 2019 as part of EPA's docket, EPA–HQ–OPP–2017–0750, Registration Review Proposed Interim Decisions for Several Pesticides, to urge EPA to remove streptomycin from registration under FIFRA because of the specter of untrammeled spread of antibiotic resistance in the environment.

12. Beyond Pesticides is also concerned about the exposure of non-target pesticide drift into waterways and its impacts on the aquatic food web and on endangered species more generally. The impact of pesticides on species is quite dramatic; animal species can suffer the same type of increases in infectious diseases as we humans, as well as suffer from acute harms from ingestion. To the extent that we have bacteria developing virulence as a result of their resistance to antibiotics, then our environment is going to see unintended secondary impacts associated with other organisms. That is deeply troubling.

13. EPA's recent approval of the widespread use of streptomycin on citrus crops represented a real blow to Beyond Pesticides' mission and work. When we are dealing with a chemical like streptomycin that has

clear associations in the scientific literature with bacterial resistance and contributes to a very real threat of pandemic from antibiotic resistance, we are contending with a public health emergency.

14. At the local, national, and international level, Beyond Pesticides works with and provides information to individuals and organizations on pesticide-related topics. Beyond Pesticides works with farmworker, environmental, and grass-roots organizations in states across the nation, including California, Florida, and Texas, to advocate for increased protections for human health and environmental quality by reducing pesticide use and promoting safe alternatives. EPA's decision to approve expanded use of streptomycin on citrus crops undermines that goal.

15. EPA's approval of widespread streptomycin use on citrus crops also undermines Beyond Pesticides' goal to protect pollinators, species, and ecosystems. Beyond Pesticides' BEE Protective program was launched in 2013 when we recognized that EPA was not performing adequate field studies to evaluate the impact that pesticides have on pollinators. The rapid population declines of honeybees and other pollinators imperil

ecosystems, economies, and the nation's food supply.

16. EPA's decision to approve the widespread use of streptomycin on citrus crops will also force Beyond Pesticides to expend time, resources, and labor on educating the agency and the public on the dangers of streptomycin. Because of EPA's harmful action, Beyond Pesticides will submit new comments to EPA on streptomycin use and the most recent scientific information demonstrating the dangers of antibiotic overuse in the environment. Beyond Pesticides will dedicate new staff resources into tracking the science around streptomycin impacts, to shine a light on the limitations and deficiencies around EPA's decision. Beyond Pesticides will also dedicate new staff resources and funds into investigating, testing, and publicizing non-chemical alternatives to managing citrus canker disease on citrus crops. We will work to publicize our findings on these streptomycin-related issues in Beyond Pesticides' publications, including "Pesticides and You."

17. EPA's approval of widespread pesticide will require Beyond Pesticides to dedicate new staff time to tracking the incidence of

streptomycin resistant diseases and updating its databases accordingly. Beyond Pesticides staff will also need to devote more attention and time to updating Beyond Pesticides' Gateway on Pesticide Hazards and Safe Pest Management on the continually evolving scientific information around streptomycin, antibiotics, and antibiotic resistant diseases and spread. Beyond Pesticides staff will spend additional time responding to member inquiries about streptomycin use and antibiotic resistant diseases.

18. Beyond Pesticides will do everything we can — through the market, through public education, through public pressure, and through support of international institutions — to try to force EPA regulators to do the right thing, to take the right action and ban the use of streptomycin on crops.

19. Beyond Pesticides is deeply concerned that the benefits of streptomycin use were overstated by EPA. Without determining the true benefit of this material, the agency is improperly allowing harm. Within vulnerable sub-population groups, the harm caused by streptomycin may be high or extraordinary. It is immoral to not conduct a very clear, defined

needs analysis or make a clear needs case before allowing the release of any toxic chemical. In the case of streptomycin, there is a whole other layer of concern given the scientifically acknowledged public health threat from antibiotic resistance. Where, as here, the agency has allowed the frivolous agricultural use of streptomycin — the unnecessary use, the use that is not justified by benefits analysis, the use that doesn't entail a proper review of externalities — the agency has failed its duty to protect health and the environment.

20. EPA's failure to adequately assess and constrain the risks of streptomycin results in poisonings, contamination, and antibiotic-resistant disease which in turn injures members of Beyond Pesticides. Some Beyond Pesticides' members are physicians whose patients are exposed to antibiotic resistance diseases.

21. Beyond Pesticides has many members who are especially vulnerable to antibiotic resistant diseases because they are elderly, immunocompromised, or otherwise have very poor health. These members will be harmed by EPA's streptomycin registration because they

will be exposed to greater numbers of antibiotic resistant bacteria through travel to citrus groves, contact with farmworkers, and the purchase and consumption of commercially grown citrus fruits. These members will additionally experience anxiety and emotional distress because of EPA's choice to endanger their health.

22. Beyond Pesticides and its members need the court to intervene to ensure that the health harms caused by widespread agricultural streptomycin use are curbed and ended. EPA has made both a political misjudgment and a scientific misjudgment. The agency is ignoring the science on adverse health effects stemming from agricultural use of streptomycin and on the availability of alternative strategies to manage bacterial diseases in agriculture.

23. A court decision reversing EPA's registration of streptomycin – or instructing the agency to follow the proper and lawful process in determining whether to register streptomycin – would redress Beyond Pesticides' members injuries by reducing the risk that they and their

patients will be exposed to antibiotic resistant bacteria created and spread by agricultural streptomycin use.

24. A court decision directing the agency to undertake a rigorous and proper examination of the impacts of agricultural streptomycin use would also redress Beyond Pesticides' and its members' injuries because it would render substantial new organizational resource diversions unnecessary and ease our members' anxiety and distress.

25. Antibiotic resistance is an existential threat. EPA has not taken the hazards of agricultural streptomycin use seriously enough, and, as a result, is now ensuring that Beyond Pesticides and its members will be seriously harmed.

26. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

SIGNED: December 16, 2021, in Washington, D.C.

Jay Feldman

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF KATHY FALCONER

I, Kathy Falconer, make the following declaration:

1. I am competent to make this declaration. I provide this declaration based upon my personal knowledge and experience. I would testify to the facts in this declaration under oath if called upon to do so.

2. I have been a dues-paying member of Beyond Pesticides since 2018.

3. I am 78 years old and reside in Visalia, California, which is surrounded by cities and towns populated with numerous commercial

orange groves, such as the cities of Exeter, Lindsay, Orange Cove, Dinuba, and Reedley. My home, in a neighborhood called The Grove, is about 10 miles from commercial orange groves bordering Exeter and about 15 miles from commercial orange groves in Dinuba.

4. I have a biology degree from California State University, Long Beach, and a master's degree from Fresno Pacific University. For 10 years, I taught science, biology, chemistry, life sciences, and earth sciences here in Visalia at the local high school, and taught mathematics for five years at a local junior high school.

5. I lived here in Visalia from 1975 to 1991, left, and then moved back in 2017. Before moving back to Visalia, I lived in Leavenworth, Washington, near the "Apple Capital of the World" in Wenatchee, Washington, for 26 years. Earlier in life, I lived in a citrus growing area, Corona, California, for about 25 years. As a result, citrus orchards and farming have always been a part of my life experience.

6. My husband is also 78 years old. We are both immunocompromised given our age and health conditions and are

therefore vulnerable to antibiotic-resistant illnesses. My past medical history includes having lip cancer removed. My husband, meanwhile, had a stroke in 2001, and the stroke has negatively impacted his health. He is physically weakened. He has suffered from pneumonia three times since 2001, and he is less resistant to air particulates.

7. My son and his two children (my grandchildren) live in Torrance, California. My son has a partial lung, and because of this, he is at much greater risk than the average person of succumbing to respiratory illness and respiratory failure, among other ailments. His health condition makes him more susceptible to developing adverse health conditions, including antibiotic-resistant infections.

8. I also have a daughter who lives here in Visalia. When she was pregnant with my grandson and for the first five years of his life, they lived less than a block away from a walnut grove that utilized harmful pesticides such as Chlorpyrifos. My grandson, who is now 11 years old, has autism.

9. I have a personal history of advocating against pesticide use in my citrus-growing region of California. This is in part because of my

grandson's autism. When I returned to Visalia from Washington, I became intensely interested in the reason why my grandson developed autism. No one else in our family has had similar cognitive or neurological issues. I began to attend conferences on pesticides, and I learned about the deeply troubling statistics on the impact of pesticides on children's health.

10. It was then, in 2017, that I joined the Coalition Advocating for Pesticide Safety ("CAPS") in Tulare County, which is a coalition of community advocates, leaders, residents, and nonprofits urging the implementation of one-mile buffer zones around schools, daycares, and labor sites from the application of certain dangerous pesticides, among other policy solutions to curb the dangerous effects of agricultural pesticide use.

11. As a member of CAPS, I participated in our coalition's effort to list the pesticide Chlorpyrifos under Proposition 65 as a chemical known to the state of California to cause reproductive toxicity. Informed by my personal experience, I also participated in advocacy against the widespread use of the herbicide glyphosate, after noticing that glyphosate residue was

present in many of the food products doctors warned my grandson against consuming, to help control his autism. I learned that glyphosate exposure can cause gastrointestinal corrosive symptoms, which in turn impacts endocrine production. Alarmed by this information, I advocated against glyphosate use on park and public grounds maintained by the city of Visalia and on the school grounds and athletic fields of the Visalia Unified School District.

12. When I was more involved in CAPS, I travelled to Lindsay and Exeter a couple of times a month to attend meetings or meet with advocates in locations surrounded by orange groves. Many of my fellow members of CAPS are the children of farmworkers, and I regularly met with people tasked with applying pesticide sprays and who witnessed the full cycle of farm citrus production on a day-to-day basis. Today, I continue to travel to Exeter, Dinuba, Reedley, and Lindsay – nearby citrus-growing locales – several times a year for appointments and to meet with friends.

13. In my experience, orange grove owners have very little concern for the health harms that could result from human exposure to pesticides. I have driven through citrus crops in the process of being sprayed with pesticides. I can smell it. I can see it, too. The pesticides look like a white powder drifting in the air. The roads cutting through the citrus orchards are two lane roads flanked by orange groves – roads on which I and my family travel. When applied, the pesticides emit a strong, pungent smell. You can close your car windows, but judging from what I see and smell, it is possible the pesticide particles could travel through the air filter, into the vehicle.

14. In addition to my own first-hand experience, I have heard of many incidents where orchard owners recklessly exposed bystanders or workers to pesticides. For instance, I have seen video evidence of a school bus full of children on the way to school driving through an orange grove while workers were applying a heavy pesticide spray on both sides of the road. Another CAPS' member – and a close friend – who has worked in

the citrus orchards for a long time, has observed a white pesticide residue powder coating oranges when picking the citrus fruits.

15. I am extremely concerned about the impact that EPA's action in registering streptomycin will have on me and my family's health. This concern is heightened because of our family's particular vulnerabilities: my husband's respiratory condition, my son's partial lung, and my grandson's autism. I am worried about both the immediate adverse effects of direct streptomycin exposure on our health, and about the spread and growth of antibiotic-resistant disease in our area linked to agricultural streptomycin use. If a member of my family suffers from a severe health condition – including an antibiotic-resistant disease – because of streptomycin use nearby, I will have to undertake substantial additional caretaking and financial responsibilities to assist them, for example, by providing health care to them or childcare assistance to my grandchildren.

16. I am anxious that I, or a member of my family, will get seriously sick or die from an antibiotic-resistant disease stemming from

agricultural streptomycin use in California. EPA's decision has put us at increased risk of that injury occurring.

17. I am also deeply concerned about the impact of EPA's streptomycin registration decision on bees. Bees are very important to me because they play a critical role in nurturing flowering plants through pollination, here in Visalia and in Fresno County more broadly. I very much enjoy observing flowering plants – such as daisies and lavender – at friends' gardens and public gardens. Just last week I visited Santa Barbara Botanic Gardens, a 78-acre garden that contains exclusively California-native plants. I view flowering plants monthly, on average, or 10 to 15 times a year, and I plan to continue doing so just as much in the future.

18. It is my understanding that some bee colonies in my area have been destroyed due to the indiscriminate use of Imidacloprid products, particularly from the spraying of Imidacloprid on crepe myrtle trees. Pesticide use is something I have advocated against to protect the bees. Because honeybees travel several miles from the hive, the bees I observe in

Visalia, Exeter, Reedley, and Dinuba may be harmed by streptomycin application on citrus crops.

19. If EPA were to vacate its decision to register streptomycin for use on citrus, my and family's health would no longer be at increased risk from direct streptomycin exposure or from the spread of antibiotic-resistant disease linked to streptomycin. Such a reversal would quell my concern and protect my family and myself. It would also help safeguard the bee populations necessary for plant cross-pollination. Furthermore, an order instructing EPA to rigorously examine the environmental and human health impacts of agricultural streptomycin use would also improve matters for me. When EPA makes a registration decision based on flawed studies, as here, then I question EPA's ability to regulate chemicals in food production. Much of my anxiety would be eased by such an instruction.

I declare under penalty of perjury, to the best of my knowledge, that the foregoing is true and correct.

Executed this 17th day of February 2022, in Visalia, California.

Kathy Falconer

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF LORI ANN BURD

I, Lori Ann Burd, state and declare as follows:

1. I am over 18 years of age, have personal knowledge of the matters asserted in this declaration and if called upon to testify would state the same.

2. I am the director of the Environmental Health program at the Center for Biological Diversity (Center).

3. The Center is a 501(c)(3) non-profit membership organization based in Tucson, Arizona with approximately 89,610 members throughout

the United States and the world, including 3,714 members in Florida, 18,375 members in California, and 2,913 members in Texas. The Center's mission is to ensure the preservation, protection, and restoration of biodiversity, native species, ecosystems, public lands and water, and public health through science, policy, and law.

4. Based on an understanding that the health and vigor of human societies, plants and wildlife, and the natural environment are deeply intertwined, the Center works to protect and secure a future for all animals and plants hovering on the brink of extinction, for the ecosystems they need to survive, and for the people that interact with, depend on, and cherish these ecosystems.

5. One of the primary mechanisms for wildlife conservation at the Center is citizen participation in species listing and protection under the Endangered Species Act (ESA). In furtherance of those efforts, the Center also takes legal, administrative, and other actions to protect imperiled species and their habitats against pollution and other threats—including toxic pollution from pesticide use—and to enable those species to recover

from the brink of extinction. Through citizen petitions and citizen lawsuits, the Center has helped to secure protection for at least 675 species and 507 million acres of designated critical habitat under the ESA, including for the Florida bonneted bat and fisher.

6. In particular, the Center's Environmental Health program, which I am the director of, works to reduce the threats posed to species and their critical habitats by pesticides and other pollutants through scientific, legal, and policy mechanisms. For example, the Environmental Health program works to enforce standards that help reduce the threat of pesticide pollution, including under the ESA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and to better inform the public of the dangers of pesticides. I strive to represent the interests of our members and the mission of the organization through the work performed by the Environmental Health program.

7. The Center cannot, of course, work on every pesticide issue in the country. Thus, we set priorities for our pesticides work. One factor we consider in setting priorities for our pesticides work is determining the

gravity and magnitude of the threats to the environment and wildlife, including species listed under the ESA. Our ability to effectively determine priorities is, in part, based on the analyses of experts, including the expert wildlife agencies of the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Services).

8. The Services' analysis usually comes through a legally required process under the ESA known as Section 7 Consultation. Under that process, a federal agency must consult with the Services if an action that it carries out, funds, or authorizes may affect ESA-listed species or habitat. When approached for consultation, the Services are required to assess whether a pesticide being proposed for approval will adversely affect ESA-listed species, jeopardize the continued existence of ESA-listed species, or adversely modify the critical habitat of ESA-listed species. The Center views Section 7 Consultation as a critical process for protecting species. Lawful consultation also provides the Center, its members, and the public (as well as the action agencies themselves) with information about what reasonable and prudent measures can be taken to avoid actions that can

jeopardize the continued existence or adversely modify critical habitat for ESA-listed species.

9. Because of the importance of Section 7 Consultation to the Center's work, the failure of the U.S. Environmental Protection Agency (EPA) to comply with the Section 7 Consultation process in approving the medically important antibiotic streptomycin for use as a pesticide on citrus crops undermines the interests of the Center and its members, and harms the Center's ability to achieve its mission and goals of wildlife conservation and ensuring a safe, secure future for all animals and plants.

10. The same is true as it relates to EPA's failure to fully analyze, as FIFRA requires, the unreasonable adverse effects on the environment from its approval of streptomycin for use as a pesticide on citrus, including effects on public health, pollinators, and farm workers. Combating the environmental and public health harms posed by pesticides is an issue that is very important to the Center and to me both professionally and personally because I understand the impacts of those pesticides. I am deeply troubled by the effects that they have on the environment, wildlife,

and human health and am aware of studies linking pesticides like streptomycin to a range of harmful impacts including through toxicity, antibiotic resistance, reproductive harm, allergic reactions, cancer, neurological problems, and other chronic effects.

11. I am further aware that pesticides, including streptomycin, can negatively affect the health of wildlife and plant life that the Center and its members appreciate conserving, viewing, and recreating around in the outdoors and find spiritual enjoyment through.

12. The Center has a long history of work analyzing the harms of pesticides on ESA-listed species, educating the public about those harms, commenting on EPA's proposals to approve pesticides for use under FIFRA, and advocating for more effective means to reduce those harms. The Center has expended a great deal of resources for over a decade seeking to rectify the EPA's failure to engage in Section 7 Consultation and comply with FIFRA's harm reduction objectives in approving pesticides such as streptomycin, and intends to continue engaging in these efforts until EPA fully comes into compliance with its requirements under those

laws.

13. In addition to its various actions under the ESA, FIFRA, and elsewhere to protect imperiled wildlife and public health, the Center is involved in a range of activities to specifically protect pollinators—including pollinators threatened by uses of streptomycin as a pesticide. The Center's native pollinators campaign, for example, ties together issues in the context of pollinator conservation to provide relevant information and action opportunities to supporters who are rightfully concerned about the health of native pollinators. In 2017, the Center produced the report *Pollinators in Peril: a systematic status review of North American and Hawaiian native bees*, which was the first-of-its-kind systematic review of the status of all 4,337 North American and Hawaiian native bees. One of the key findings of that report is that agricultural intensification, which includes habitat destruction and pesticide use, is a key driver in native bee declines. Native and imperiled bee species such as the yellow carpet solitary bee (*Andrena blennospematis*) in Central California and sunflower leafcutting bee (*Megachile fortis*) in areas including Texas face key threats from pesticide

exposure.

14. In short, several of the issues and mission-specific goals that are important to the Center intersect with the EPA's unlawful approval under the ESA and FIFRA of streptomycin for use as a pesticide on citrus crops, including reducing the impacts of pesticides on the environment, imperiled wildlife, and pollinators; protecting public health and ecosystems from streptomycin pollution and antibiotics resistance; and seeking to see EPA comply with its Section 7 Consultation obligations under the ESA in approving new pesticide uses. The Center is substantively and procedurally injured by EPA's failures in this regard.

15. The Center also has members who live, recreate, and work in the areas where streptomycin is approved for use; who regularly enjoy bird watching, boating, and wildlife viewing (including for threatened and endangered species) in these areas; and who are themselves in fact injured because of EPA's substantive and procedural failures to comply with the ESA and FIFRA in approving streptomycin for use on citrus crops.

16. An order from the Court vacating EPA's approval for the use of streptomycin as a pesticide on citrus crops and requiring the agency to fully assess streptomycin's risks as required by the ESA and FIFRA, would remedy the injuries experienced by the Center and its members. Such an order would help guarantee that EPA will act lawfully under the ESA and FIFRA to protect species, as well as the environment and public health, that may be harmed by streptomycin use. Participation of the Center's individual members in this lawsuit is not required to achieve this requested relief.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 17, 2022 in Tucson, Arizona.

Lori Ann Burd

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF ILEENE ANDERSON

I, Ileene Anderson, make the following declaration:

1. I provide this declaration based upon my personal knowledge. I would testify to the facts in this declaration under oath if called upon to do so. As to those matters which reflect an opinion, they reflect my personal opinion and judgment on the matter.

2. I am a resident of Los Angeles, California. I have a Master of Science in Biology from the California State University at Northridge. I

have studied and surveyed for native species in California for over 30 years, and have researched, surveyed for, studied, observed, and sought protection for many imperiled species, both plant and animal. In addition, I have researched many rare and listed (threatened or endangered) California plants and animals, and their habitat needs, including the San Joaquin kit fox, Buena Vista Lake ornate shrew, California red-legged frog, and Southern California steelhead Distinct Population Segment.

3. I am a member of the Center for Biological Diversity (Center) and have been since 1999. I have also been on staff as a scientist with the Center since 2005. Before my tenure at the Center, I was the Southern California Regional Botanist for the California Native Plant Society (CNPS) from 1997 to 2005. From 1995-2005, I also worked as an independent botanical consultant throughout the southwestern U.S.

4. I understand that the Center's mission is to ensure the preservation, protection, and restoration of biodiversity, native species, ecosystems, public lands and water, and public health through science,

policy, and environmental law. I support these goals, as well as the Center's mission and approach to wildlife conservation.

5. I read the Center's newsletters and press releases and respond to online petitions and action alerts created by the Center that allow me to engage in matters that I care about related to wildlife, public health, and environmental protection. I rely on the Center, in part, to represent my interests in conserving endangered species and their habitats.

6. I believe the U.S. Environmental Protection Agency's (EPA) decision to approve the medically important antibiotic streptomycin for use as a pesticide on citrus crops in California and elsewhere will harm the environment, wildlife, and human health. I am especially concerned about this decision because I am aware that the EPA approved the use of streptomycin as a pesticide without first consulting on its decision with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (Services), as required by the federal Endangered Species Act (ESA).

7. I personally care about seeing federal agencies comply with the ESA because of the protections the Act affords to the species in California

and elsewhere that matter most to me. Complying with the ESA ensures that agency actions, including the EPA's streptomycin approval, will not jeopardize a species' survival or recovery in the wild, including species that I care deeply about and have worked for decades to protect and recover. For example, if the EPA had consulted on this approval, I believe that consultation would have provided the scientific data necessary to identify if and to what extent use of streptomycin as a pesticide on citrus crops is a stressor on critically imperiled species such as the San Joaquin kit fox that are already well down the path towards extinction because of existing threats.

8. I work in a professional capacity and personally to protect and restore California's rich and unique biodiversity, especially in the southern and central parts of California that are home to one of the country's largest citrus industries. As detailed below, I am particularly concerned with maintaining important habitat for rare San Joaquin kit foxes, Southern California steelhead, California red-legged frogs, and Buena Vista Lake ornate shrews, and believe that my personal and professional interests in

observing and conserving these species are harmed by EPA's failure to consult under the ESA in approving streptomycin for use on citrus crops.

San Joaquin Kit Fox

9. The San Joaquin kit fox is a critically endangered species endemic to California's central San Joaquin Valley and adjacent arid grasslands. This diminutive canid has been protected under California and federal law for over forty years, yet no consistent monitoring of populations is being implemented and the data that is available indicates that the species population continues to decline. I believe that the kit fox's current patchy distribution on the landscape coupled with ongoing habitat alteration, environmental threats, disease, and climate change could very easily lead to local extirpation and a drift towards species extinction if further efforts are not taken without delay to protect this species.

10. I have researched, studied, observed, been trained to survey for, surveyed for, and sought protections for the kit fox. I have conducted various research projects on this declining species throughout its shrinking range. For example, I was part of the Center's team that petitioned the U.S.

Fish and Wildlife Service to designate critical habitat for the highly imperiled San Joaquin kit fox and am aware that the kit fox's habitat has already been reduced by approximately 90 percent due to conversion to agriculture and urbanization in the San Joaquin Valley—a percentage that has only gotten more dire in the last few years due, in part, to further habitat fragmentation.

11. Today, the kit fox's remaining habitat patches are often contiguous with agriculture, including citrus groves, in the San Joaquin Valley. While the San Joaquin kit fox does not raise pups within the groves, the fox can use agricultural areas including citrus groves (and particularly the peripheries of the groves) as movement corridors. As a result, the kit fox can come into direct contact with streptomycin pesticide spraying practices in citrus groves, and I believe can suffer direct and indirect harm from that exposure—harm that would have been analyzed and addressed had EPA consulted with the U.S. Fish and Wildlife Service under the ESA.

12. I am deeply concerned that the use of streptomycin on citrus groves will impact San Joaquin kit fox populations, which will directly

harm my interest in observing, conserving, and enjoying this species. I believe the EPA should fully analyze the potential impacts of the use of streptomycin in citrus groves on the endangered kit foxes particularly where native habitat for the kit fox is directly adjacent to citrus groves or where kit foxes are using citrus groves as movement corridors. The San Joaquin kit fox is already being impacted by numerous threats including habitat development, climate change effects, pesticide use, predation, disease, and road mortality. Without EPA dutifully evaluating the impacts of streptomycin in citrus groves in the range of the San Joaquin kit fox, the use of streptomycin may result in yet another impactful stressor to this highly imperiled species.

13. To satisfy both my personal and professional interests, I have looked for San Joaquin kit fox in the San Joaquin Valley and surrounding areas and have had the opportunity to observe them many times and document their burrows and presence. For example, I have set up tracking stations outside of San Joaquin kit fox characteristic keyhole shaped burrows (Figure 1).

14. Because San Joaquin kit fox are primarily nocturnal, I also have set up and used bait stations to detect their (and other carnivores') presence. Figure 2 shows a picture I took of a bait station with tracking material that will capture animal tracks for identification.

15. Because San Joaquin kit fox are primarily nocturnal, they can be difficult to photograph, but I have seen them during "spotlighting" trips where I shine a spotlight on them (and other nocturnal wildlife). I have also set up wildlife camera "traps" in order to document their presence.

16. My most recent field work on the kit fox occurred just prior to COVID-19 restrictions being put into place, in February 2020. I looked for kit foxes and signs of kit fox at three locations in Kern County, which has one of the highest amounts of citrus groves in the state. I intend to return to look for kit fox and its habitat in 2021 once restrictions from the pandemic

have eased, and will be injured if I cannot see them, even in part, because of EPA's approval of streptomycin for use on citrus fields.

17. The San Joaquin kit fox is a species that is, in my opinion, critically endangered. Kit fox population levels have been low since before the ESA was enacted, yet no regular rangewide census is done by California or federal wildlife agencies despite the San Joaquin kit fox being protected for over 40 years by both the state and federal ESAs. Absent consistent survey data, it is challenging to evaluate the status of the San Joaquin kit fox's population. But based on habitat destruction and the decline in sighting, it appears that the species' population is still in decline. I worry that any additional agricultural threats will further harm San Joaquin kit fox populations. Poorer health could exacerbate resistance to disease, including mange. In my opinion, the San Joaquin kit fox desperately needs focused recovery efforts throughout its remaining range, not additional habitat destruction and direct threats.

Buena Vista Lake Ornate Shrew

18. The federally endangered Buena Vista Lake ornate shrew is a tiny mammal only known to live on 11 sites in the southern portion of the San Joaquin Valley, California. Because of agricultural encroachment and other habitat losses, the shrew's remaining habitat consists of patchily distributed remnants of wetland and riparian habitat. The shrew relies on this remaining habitat to persist with moist soils, dense groundcover, and diverse prey populations of insects, earthworms, and other small invertebrates.

19. Water that now sustains some of the remnant patches of the shrew's diminishing habitat often comes from agricultural runoff from adjacent industrial agribusiness. Citrus groves are included in the matrix of agriculture in the San Joaquin Valley that contributes to runoff, but the full effects to the shrew of using streptomycin as a pesticide on citrus groves are not known in large part because the EPA failed to engage in consultation with the Service prior to approving this pesticidal use.

20. I am concerned that agricultural runoff from citrus groves from the spraying of streptomycin will end up in the habitat of the Buena Vista Lake ornate shrew, including federally designated critical habitat, and will have negative direct and indirect impacts on shrew populations. I have repeatedly looked for Buena Vista Lake ornate shrew in its habitat over the past fifteen years in hopes of seeing and photographing a shrew but have yet to see one. I plan to continue looking for shrews and deeply hope to finally get a chance to see one. For example, I intend to visit the San Joaquin Valley this spring to visit several of the publicly accessible locations where the Buena Vista Lake ornate shrew has been documented. Several of those sites also have San Joaquin kit foxes present, so I will also be looking for kit foxes at the same time and am hopeful that I may see one or more. I will be doing night surveys in order to try to see those species. Any harm to this adorable, pointy-nosed little shrew as a result of the EPA's actions will injure my aesthetic, scientific, and conservation interests in seeing and experiencing the species and its persistence.

21. The Buena Vista Lake ornate shrew is already being impacted by numerous threats including agricultural and urban development, insufficient water supply, potentially toxic levels of selenium in various water sources, pesticides, and inbreeding depression. Without EPA dutifully evaluating the impacts of streptomycin in citrus groves in the range of the Buena Vista Lake ornate shrew, the use of streptomycin may result in yet another impactful stressor to this highly imperiled species.

Southern California Steelhead

22. As a scientist, I am aware that the Southern California steelhead is a critically endangered anadromous fish species endemic to southern California's coastal tributaries. Southern California steelhead have unique genetics and are more genetically diverse than other steelhead, enabling the National Marine Fisheries Service to identify them as an endangered Distinct Population Segment (DPS). Their genetic diversity is an important characteristic that may enable steelhead to better adapt to climate change and the warming waters that will occur from our changing climate. The DPS is very limited in accessible spawning and rearing habitat due to

hydrological alterations. The Southern California steelhead DPS current low abundance coupled with lack of access to historic spawning and rearing habitat and ongoing habitat degradation is pushing this DPS closer to extinction.

23. I am concerned that the use of streptomycin on citrus groves will have direct and indirect impacts on the Southern California steelhead DPS through runoff of sprayed streptomycin into the waterways that steelhead depend on—impacts that would have been analyzed had EPA consulted with the Services under the ESA prior to approving this use. The southern California river with the fewest migratory impediments to the Southern California steelhead's DPS is the Santa Clara River in Ventura and Los Angeles counties. The Santa Clara River meets the Pacific Ocean in Ventura County between the cities of Ventura and Oxnard. Upstream the steelhead meet only a single diversion—the Freeman Diversion—that currently prevents most all steelhead passage. I have been involved for years in improving the fish passage at the Freeman Diversion, because the Santa Clara River is the best free-flowing southern California river for

Southern California steelhead recovery as identified in the NMFS' Recovery Plan for the DPS. Upstream of the Freeman Diversion, the Santa Clara River is flanked on both sides by agriculture including citrus groves. Much of the agricultural runoff is shunted into the Santa Clara River and ultimately finds its way downriver to the Pacific Ocean.

24. I have repeatedly looked for Southern California steelhead in their local habitat when they return to the rivers to spawn over the past ten years in hopes of seeing and photographing the species but have yet to see one. I plan to continue looking for steelhead and deeply hope to finally get a chance to see one. For example, I am planning a trip to the Santa Clara River when adequate rains occur, and flows increase in the river in order to try to see steelhead at the base of the Freeman Diversion or in pools between the Pacific and the Freeman diversion. Any harm to this already imperiled steelhead population as a result of streptomycin runoff and exposure will harm my aesthetic, scientific, and professional interests in observing and conserving this species. Without EPA dutifully evaluating the impacts of streptomycin from citrus groves in the range of the Southern

California steelhead DPS, the use of streptomycin may result in yet another impactful stressor to this highly imperiled species that desperately needs recovery.

California Red-Legged Frog

25. The California red-legged frog is a famous and iconic California native amphibian, memorialized in Mark Twain's short story, "The Celebrated Jumping Frog of Calaveras County." Tragically the California red-legged frog has suffered great declines to the point where it is listed as a threatened species under the ESA. I am aware that the Center has worked to secure critical habitat designations to protect the California red-legged frog, and I have worked specifically on several projects in central and southern California to protect key breeding drainages from impacts of poor water quality, siltation from development projects, adequate water quantity, and other threats to the species.

26. In southern California, the California red-legged frog lives and breeds in the Santa Clara River and its tributaries. I have looked for and seen California red-legged frogs only a couple of times in my life, and that

makes me so sad to think that they used to be one of the most common amphibians in California.

27. I am concerned that the use of streptomycin on citrus groves will have direct and indirect impacts on the California red-legged frog through runoff of sprayed streptomycin into the waterways that this rare amphibian depends on—impacts that would have been analyzed had EPA consulted with the Services under the ESA prior to approving this use. This is a water-dependent species and I believe that contaminated water coming off of the orange groves could literally wipe out a sub-population. The frogs are already being impacted by numerous threats including habitat degradation, climate change, pesticide use, predation, disease, and road mortality. Without EPA dutifully evaluating the impacts of streptomycin in citrus groves in the range of the California red-legged frog, the use of streptomycin may result in yet another impactful stressor to this highly imperiled species.

28. Because amphibians are in crisis worldwide, I believe that doing everything we can to conserve our local endemic amphibians including the California red-legged frog is essential.

29. Agribusiness, including citrus farming, in central and southern California has already damaged or permanently destroyed wildlife habitat for species that I care deeply about, contaminated California's water sources with pesticides, and diminished my enjoyment in watching wildlife and looking for plants. Any further damage to the species discussed above and their habitats as a result of EPA's action here would negatively affect my aesthetic, spiritual, recreational, and moral interests.

30. I take great pleasure in knowing that these species exist in the world, even when I can't always find them in their habitats and feel morally obligated to give these species a voice and protect them against extinction. I fear that, and will be injured if, in the places where I used to seek and enjoy observing—or trying to observe, as is the case with the Buena Vista Lake ornate shrew and Southern California steelhead—these

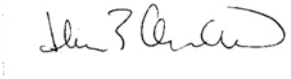
species they will no longer be present, and that my life and those of others that come after me will be diminished.

31. In addition to harming wildlife, I think that it is reckless to use an antibiotic so important to human medicine on citrus trees. I believe EPA's decision to allow streptomycin to be sprayed onto citrus crops, where it can drift or runoff into the surrounding environment, will have implications on human health and safety in California, including as it relates to the potential spread of antibiotic resistance because of this approval. In my opinion, streptomycin should be used sparingly for human use, and not for agricultural purposes. I believe that the injudicious use of antibiotics, which I consider using streptomycin to treat citrus groves to be, will likely create antibiotic resistant super-bugs which will come around to cause greater harms to humans and all living things.

32. EPA's action here causes direct injury to my aesthetic, conservation, recreational, scientific, educational, and moral interests, and potentially my health. I will continue to be adversely affected and injured if EPA continues to fail to consult with the Services on impacts to these

species under the ESA. I am also harmed by EPA's failure to adequately consider harms to human health from antibiotic resistance and direct exposure as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prior to approving these streptomycin uses. These are actual, concrete injuries that are caused by EPA's failure to comply with the ESA and FIFRA when registering streptomycin as a pesticide for use on citrus crops in Florida and elsewhere.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct and that this declaration was executed on February 22, 2022 at Los Angeles, California.



Ileene Anderson

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF CHRISTINA R. CELANO

I, Christina R. Celano, declare as follows:

1. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify competently thereto.

2. I am over the age of 18 and I currently reside in Florida where I have lived for nineteen years. I moved to Florida in large part because of its abundance of wildlife.

3. I work as a professional wildlife photographer in Florida. I stand or sit in my kayak for hours at a time in the rivers, bays, and

mangroves all around Florida, including downstream of major citrus producing areas, to take images of birds or any living thing that catches my eye.

4. I have been a member of the Center for Biological Diversity since 2009. The Center is a non-profit organization committed to the preservation, protection, and restoration of native species and the ecosystems upon which they depend. As a member of the Center, I participate in action alerts and read the newsletters to be more informed. I rely upon the Center to represent my interests in protecting endangered species and their habitat.

5. I am concerned about pesticide impacts on endangered and threatened species. Pesticides harm ALL species. That is what they were designed to do . . . KILL. Whatever we put into the environment ends up in our bodies. If it affects any species in a negative manner, it will eventually affect humans. I am concerned about the pesticides used on the major agricultural crops in Florida, including oranges, sugarcane, hay, and different kinds of fruits and vegetables. Because of the breadth of

agriculture in Florida and the number of pesticides used I believe that the individual and cumulative effects on rare wildlife species are widespread.

6. I am particularly concerned about the impact of pesticides on the imperiled species that I regularly photograph or seek to photograph. These include:

Mammals

Florida panther (*Puma concolor coryi*)
Florida bonneted bat (*Eumops floridanus*)
Florida salt marsh vole (*Microtus pennsylvanicus dukecampbelli*)
West Indian manatee (*Trichechus manatus*)

Birds

Audubon's crested caracara (*Polyborus plancus audubonii*)
Cape Sable seaside sparrow (*Ammodramus maritimus mirabilis*)
Everglade snail kite (*Rostrhamus sociabilis plumbeus*)
Florida grasshopper sparrow (*Ammodramus savannarum floridanus*)
Florida scrub jay (*Aphelocoma coerulescens*)
Piping plover (*Charadrius melodus*)
Roseate tern (*Sterna dougallii dougallii*)
Wood stork (*Mycteria americana*)

Reptiles

Atlantic salt marsh snake (*Nerodia clarkii taeniata*)
American crocodile (*Crocodylus acutus*)
Bluetail mole skink (*Eumeces egregius lividus*)
Eastern indigo snake (*Drymarchon corais couperi*)

Sand skink (*Neoseps reynoldsi*)

7. I have yet to see a Florida panther, a very elusive animal with an incredibly low population. To me, the seriously imperiled panther is akin to a remarkable mythical creature because it is one of the last big cats to survive in the wild in the United States. If I had the opportunity to photograph a panther I would be overcome with joy, but I am concerned I will not get the opportunity to see and photograph one because of the significant threats that wild panthers face on a daily basis. I have traveled and continue to travel to parts of Florida where the panther has been seen but its habitat is fractured or destroyed by overdevelopment and agriculture. The last remaining panthers are now experiencing even greater threats because of this newly approved use of streptomycin as a pesticide. This harms me and my interests in observing a panther.

8. I travel to the Everglades often, which is habitat for a range of endangered species, such as,

a. The American crocodile

b. The wood stork

c. The West Indian manatee

d. As well as the Northern Harrier with the endangered Florida

Salt Marsh vole clutched in its talons.

9. The animals of the Everglades and Florida Bay provide me with an education, an income, and more joy than anything else I have experienced in my 60 plus years of life.

10. I have snorkeled with, kayaked among, and photographed the West Indian manatee. The experience is always amazing, and I look forward to future encounters with this imperiled mammal.

11. My photography focuses on a number of species, including birds and pollinators. I have had the pleasure of observing several imperiled bird species, including Audubon's Crested Caracara, Cape Sable Seaside sparrow, Everglades Snail kite, Florida Grasshopper sparrow, Florida Scrub jay, Piping plover, Roseate tern, and Wood stork, as well as many pollinators, including honeybees, native bees, and dragon flies.

12. Below is one my photographs of a honeybee gathering pollen on a Buccaneer palm tree blossom. It fills me with joy to see and photograph these species, and it injures me to know that my continuing ability to do so may be negatively impacted by the spraying of streptomycin as a pesticide.

13. I have also observed several endangered reptile species, including, the American crocodile, bluetail mole skink, eastern indigo snake, and sand skink. I have seen and photographed the Atlantic salt marsh snake on many occasions, sitting motionless on the bottom among mangrove roots, waiting for prey. Snakes are misunderstood and underappreciated by most of the human race. A great shame, as they are elegant in movement, fascinating to observe, beautiful in their simplicity of design, and beneficial to the ecosystem—eating many insects, rodents, and even other reptiles.

14. I spend 330 plus days per year outside to take, or prepare to take, photographs for my living, and I travel to the habitat of the species listed in this declaration on a daily basis. On these visits, currently and into the future, I will continue to seek out opportunities to observe and photograph all of the species listed in this declaration. Further harm to these species as a result of streptomycin use will harm my recreational, aesthetic, and professional interests in these species.

15. As discussed further at paragraphs 3 and 18, I spend time in and around citrus fields where streptomycin may be used as a pesticide photographing species such as the Audubon's crested caracara and paddling in waterways that could receive runoff from streptomycin spraying. I strongly believe that the use of pesticides like streptomycin in and around habitat for these species is harmful and reduces the likelihood that I will be able to observe them in the future. Every species, including humans, are part of a complex ecosystem. If we lose one species, others that depend on it for their survival will also disappear. Within the unique ecosystem of the peninsula we call Florida, indigenous species are in

decline due to ignorance and unintentional or intentional poisoning from humans who do not understand how important they are to our continued existence on this planet.

16. The use of pesticides in essential wildlife habitats, or in agricultural areas that affect these essential habitats, endangers all life forms and most certainly the recovery of threatened and endangered species. I find that fact to be abhorrent, and it most certainly injures my interest in seeing and enjoying these species.

17. I am also concerned about the effects of pesticides on my health. I understand that streptomycin is considered by the World Health Organization as being an antibiotic considered to be critically important to treating diseases such as tuberculosis in humans. I don't believe such an important antibiotic should be approved for use as a pesticide and am specifically concerned about the effects of these pesticidal uses on my health. Indeed because I am concerned that exposure to pesticides will harm my health, for the last 30 plus years I have only purchased organically produced foods and personal care products.

18. I would also be more comfortable, and less concerned about negative impacts to my health from exposure, when photographing in and around citrus fields if pesticides, including streptomycin, were not used. For example, I get special joy from photographing the Audubon's crested caracara, a species that is listed as threatened under the federal Endangered Species Act. Because the species is often found in and around citrus fields, I often find myself in close proximity to these fields when I am photographing caracaras. Sometimes I will sit down, or often lay down on the ground to get the best photograph of these magnificent birds, but I am concerned about potential exposure to pesticides such as streptomycin being sprayed on the crops and that may drift onto the nearby fields and roadways where I am sitting. These concerns, and especially the potential risks to my own health from exposure to streptomycin, harm me and reduce my enjoyment in photographing these species that I love. Here is an example of a photo that I took at the at Kissimmee Prairie Preserve of an Audubon's crested caracara.

19. Because I work as a wildlife and nature photographer, I have a strong professional and economic interest in the preservation of imperiled wildlife and habitat, including the species listed in this declaration. I have been a professional photographer for over 15 years, and I depend upon intact and healthy ecosystems to provide subjects to photograph. If the species listed in this declaration or those species that depend on them suffer further declines or become extinct, I could lose my livelihood.

20. The loss of species in the ecosystem of Florida would also negatively affect the area as a tourist destination due to the fact that many people travel here to see wildlife. A reduction in tourism would impact my ability to sell my images to these visitors.

21. I have an aesthetic interest in protecting all of the species listed in my declaration. I find nature and all species to be stunningly beautiful. I am captivated by and joyful in witnessing species' behaviors and am ever hopeful in my efforts to view more secretive species and their behaviors.

22. I have a moral and spiritual interest in protecting these species. I find it unconscionable when animals—individuals or whole species—perish due to the ignorance and/or greed of a few human beings. I believe that all animals have a right to live and that they should be treated with the respect they have earned for survival despite humanity's detrimental interference. I also believe that the biodiversity of Earth is of the utmost importance to all its inhabitants.

23. As someone who is deeply concerned about the fate of imperiled wildlife, I am upset that the Environmental Protection Agency has refused to consult with the U.S. Fish and Wildlife Service about the impacts of pesticide registrations, including streptomycin, on the rare species included in this declaration. It is another example, among many, of the U.S. government's failure to properly communicate between branches!

Without consultation, the Environmental Protection Agency cannot understand the full impacts to species of its action. And as a result, the Environmental Protection Agency has not taken all available steps to ensure that use of pesticides, including streptomycin, does not harm or kill these species.

24. In sum, I have professional, economic, aesthetic, spiritual, and moral interests in the preservation of the species listed in this declaration, their habitats, and other species that I photograph and enjoy. These interests are being harmed by the Environmental Protection Agency's failure to consult with the U.S. Fish and Wildlife Service on impacts of streptomycin's registration on these species. Specifically, I believe that the Environmental Protection Agency's failure to follow the law makes these species more likely to suffer further population declines. If these species decline or become extinct, the loss would deprive me of the benefits I currently enjoy from the existence of these rare animals. An order from the Court vacating EPA's approval for the use of streptomycin as a pesticide on citrus crops and requiring timely consultation with the U.S. Fish and

Wildlife Service could result in protective measures aimed at reducing impacts of streptomycin on these species, and would ensure that my interests in these species and the species themselves are preserved.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 15, 2022 in Chiefland, Florida.

Christina R Celano

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF BECKY AYECH

I, Becky Ayech, make the following declaration:

1. I am the president of the Environmental Confederation of Southwest Florida (ECOSWF), a nonprofit organization whose mission is to conserve, maintain, and protect the environment and the people and wildlife within it.

2. I am competent to make this declaration. I submit this declaration based upon my personal knowledge and previous five years of work experience in the medical field as a nursing assistant. I would testify

to the facts in this declaration under oath if called upon to do so. I submit this declaration in support of the legal challenge, in which ECOSWF is a Petitioner, to the Environmental Protection Agency's (EPA's) unconditional registration of the use of streptomycin sulfate on citrus.

3. I reside on a farm in Sarasota County, in southwest Florida, where I have lived for over 42 years.

4. I have been a member of the Environmental Confederation of Southwest Florida (ECOSWF) since 1982. My desire to join ECOSWF was a natural outgrowth of my upbringing, which emphasized being a good steward of the environment and taking care of the living creatures within it. I am currently the president of ECOSWF and have been for the past 27 years.

5. ECOSWF is a nonprofit comprised of various environmental organizations and individuals, and its mission is to protect the air, water, lands, and diverse plant and animal species of southwest Florida for the benefit of people, wildlife, and the environment itself.

6. ECOSWF has nine organizational members,[1] and because we count the individuals from each member organization as ECOSWF members, we have thousands of individual members overall. An organization becomes a member of ECOSWF by paying an annual fee of $25 and affirming a commitment to our mission statement. We also have a handful of individual members not affiliated with any organization, for whom the membership process is the same.

7. ECOSWF's members are the backbone of our organization, providing financial support, bringing environmental issues to the attention of the organization, and engaging in educational initiatives. Members also meet with government officials to provide information about our positions, and they participate in litigation at the state and federal level. ECOSWF is

[1] ECOSWF's organizational members are: Coastal Wildlife Club, Control Growth Now, Sierra Club Florida Greater Charlotte Harbor Chapter, Highlands County Audubon, Sierra Club Florida Manatee-Sarasota Chapter, Florida Native Plant Society Mangrove Chapter, Miakka Community Club, Responsible Growth Management Coalition, and Save Our Creeks.

led by a smaller subset of its members who make up the Board of Directors, which meets monthly.

8. As president of ECOSWF, I manage the operations of the organization, host monthly board meetings, lead discussions on which issues we will engage in, and lead and organize educational efforts.

9. Fighting against chemicals that are harmful to human health and the environment is an ongoing, core part of ECOSWF's mission. At the proposed rule stage, ECOSWF strongly opposed EPA's plans to approve this new use of streptomycin due to the flaws and inadequacies in EPA's human health risk assessment.[2]

10. ECOSWF has advocated against the use of harmful chemicals, such as roadside ditch cleaners that are harmful to native plants, and pesticides that are harmful to aquatic vegetation and species. Our organization also monitors and has been in conversations with state and local agencies about the use of the pesticides and herbicides, including

[2] See Ex. A, "Comments Opposing EPA's Proposed Registration Decision for the New Use of the Active Ingredient Streptomycin Sulfate[.]"

Malathion, DDT, and Roundup, over concerns about their harmful effects on people, animals, and the environment.

11. We are also active in efforts to protect endangered species. For example, we are currently a plaintiff in a legal challenge to the expansion of roadways in Florida panther habitat. Increased vehicle traffic and decreased natural habitat puts panthers' lives at risk, and these projects failed to properly consider impacts to panthers or put legally required protections for them in place. We have also submitted numerous comments over the years to federal and state agencies on issues affecting wildlife, such as proposed phosphate mining that could impact the habitat of endangered species and proposed rules that were not protective of gopher tortoises, among others.

Health Risks from the Use of Streptomycin on Citrus.

12. ECOSWF is strongly opposed to EPA's approval of the use of streptomycin on citrus because of the known and unknown health risks that ECOSWF members face from exposure to this antibiotic. ECOSWF is

also concerned that the use of antibiotics on citrus in the manner approved by EPA will lead to an increase in antibiotic resistance.

13. My own personal near-death experience three-and-a-half years ago makes the fear of antibiotic resistance all too real: I was diagnosed with sepsis, a life-threatening illness that can only be treated with antibiotics. The only reason the treatment was successful is because the bacteria that infected me had not developed a resistance to antibiotics. If the bacteria had become resistant, I doubt antibiotics would have saved my life in this instance.

14. When I was being treated, I had an abscess into which doctors made an incision. Now, a hernia has developed in my abdominal wall where the incision was made, which is being monitored and may need to be repaired surgically. This would be a very delicate surgery given the location, and complications could arise that could require the use of antibiotics.

15. ECOSWF members, including myself, are deeply worried about the known and unknown health risks from exposure to streptomycin.

Known health risks, discussed in our comments to EPA, include allergic reactions and irritation to the skin and eyes, toxicity to the kidneys, toxicity to the inner ear, and increased antibiotic resistance. Moreover, EPA did not account for people like me and the ECOSWF members who face exposure to streptomycin because we live near citrus groves, spend a significant amount of time outside, and live in such a way that we are connected to the land. There may be unknown added risks resulting from this added exposure through the air we breathe, the water we drink, and the food we eat.

Exposure to streptomycin on my farm and in town:

16. Old Miakka, where I live, is a rural part of southwest Florida that is home to abundant natural areas and agricultural lands, including several citrus groves.

17. My husband and I live on a 5-acre farm in a 68-year-old farmhouse. We raise chickens and sheep and grow our own vegetables. We currently have 50 sheep, 48 chickens, and a one-acre vegetable garden[3].

18. Our farming lifestyle is such that we are outdoors every day. Whether taking care of the animals, tending to our vegetable garden, or keeping our windows and doors open because we do not have air conditioning, our lives are very connected to the land and environment.

19. The eastern boundary of my property is only 1500 yards from a citrus grove, which is one of three groves near our home. And my entire property is within one to two miles of the grove. When the citrus trees bloom, we can smell the blossoms from our home, and when chemicals are sprayed on the trees, we can smell those as well.

[3] We grow snow peas, carrots, kale, tomatoes, eggplant, green beans, cabbage, peppers, mustard, okra, fennel, spinach, lettuce, pumpkin, squash, broccoli, and onions. The vegetable garden primarily supplies food for my husband and me, and of the vegetables we do not eat, we sell or give away.

20. There is also a second orange grove that is about a half-mile away from my property, and it runs alongside the main road to the local post office. And a third orange grove is next to the local animal feed store where ECOSWF members and I regularly go.

21. Because streptomycin will be applied via air blast spray, I fear exposure through drift after it is sprayed and that there will be no way to escape it.

22. At my property, I am worried about further exposure from handling and taking care of my animals, as they may carry antibiotics from drift that settles on them.

23. I am also concerned about exposure to streptomycin via rain runoff. In Florida, we experience three to four months of heavy rains each year. Every time it rains, there is water runoff and sheet flow, and this could capture streptomycin residue from the nearby grove and carry it onto my property.

24. ECOSWF members face these same exposures at my property when they come to visit. We host monthly ECOSWF board meetings at my

home, and members also come over for special and annual meetings. In addition, members regularly enjoy bringing their children and families to my farm to see our sheep, bottle-feed lambs, hold chickens, search for eggs, and take photos of our garden.

25. I am also fearful that streptomycin may contaminate my vegetable garden either through spray drift or from soil fertilized with manure from my sheep that may have been exposed to streptomycin. I would then face additional exposure to antibiotics whenever I eat those vegetables. And given that I regularly give away or sell my vegetables to ECOSWF members, they too share these fears.

26. I have these same concerns about the eggs produced on my farm. If streptomycin gets into my chickens' food and water supply, the eggs may be contaminated with antibiotics. I regularly eat eggs from my chickens, and I sell or give them away to ECOSWF members, and thus we are worried about exposure from this source as well.

Potential contamination of our water supply:

27. ECOSWF members are further concerned about the risk of streptomycin exposure through our drinking water.

28. The counties in which ECOSWF works and our members live – Charlotte, Manatee, Sarasota, and DeSoto counties – primarily receive their drinking water from the Peace River. The river also serves as a back-up source of water for other communities in the region. Because stretches of the Peace River are lined with citrus groves, ECOSWF members are concerned that their drinking water supply will be contaminated by streptomycin.

29. Drinking water sources in our region have been polluted in the past by irrigation runoff from citrus groves,[4] raising our fears that this harm will occur again with streptomycin.

[4] See, Kate Spinner, "State money is encouraging landowners to dig pits to collect water for irrigation," The Sarasota Herald-Tribune (Feb. 20, 2007), https://www.heraldtribune.com/news/20070220/dirt-mine-boom ("Too many farmers in east Charlotte and parts of DeSoto County are using low-quality, salty well water to irrigate their groves. The ground-water pumping has polluted Shell and Prairie creeks, which Punta Gorda uses for public water supplies, with high salt levels.").

30. Although we are aware that water is treated before public use, ECOSWF is concerned that such treatment would not completely eradicate antibiotics. Antibiotics can persist in wastewater after treatment, suggesting the same would be true in freshwater.[5]

Antibiotic Exposure When Recreating and Harms to Species.

31. ECOSWF is concerned about the risks of harm to the species that our organization strives to protect, and that our members enjoy observing when they recreate. And we are also concerned about increased exposure to the antibiotic when spending time in areas near citrus groves.

32. Southwest Florida is an environmentally unique and diverse ecosystem filled with nature preserves, wildlife sanctuaries, marshes, waters, and wetlands. Neighboring the iconic Everglades National Park and the Big Cypress National Preserve, the region is a hotspot of biodiversity, containing many endangered and threatened species that are

[5] Shen, Yanru, et al., "Degradation of streptomycin in aquatic environment: kinetics, pathway, and antibacterial activity analysis. *Environmental Science and Pollution Resources*, Volume 24, Pages 14337–14345 (2017), https://doi.org/10.1007/s11356-017-8978-5.

federally protected, such as the highly endangered Florida panther, of which there are only a few hundred remaining; wood stork; white ibis; little blue heron; bonneted bat; smalltooth sawfish; gopher tortoise; pileated woodpecker; indigo snake; and the Florida scrub jay.

33. EPA did not evaluate whether or how streptomycin use on citrus would impact species or the habitat they rely on to survive. ECOSWF is concerned that the wildlife the organization strives to protect and that our members enjoy observing could suffer harms from the use of streptomycin on citrus.

34. Additionally, ECOSWF members are worried about additional harms to our health from exposure to streptomycin when recreating at natural areas near orange groves.

35. The Myakka River State Park, the Old Miakka Preserve, and the Peace River are popular recreation spots for ECOSWF members and me that are near citrus groves. ECOSWF members, including myself, regularly visit the park to enjoy hiking, kayaking, observing wildlife, and fishing. At the Old Miakka Preserve, which consists of environmentally sensitive

lands, ECOSWF members and I enjoy hiking, birdwatching, and observing wildlife. And the Peace River is a popular recreation spot where ECOSWF members and I regularly enjoy kayaking, canoeing, swimming, and fishing.

36. When I go to these locations, I particularly enjoy hiking, riding my bike, and observing wildlife. At these scenic environmental spots, I enjoy observing Florida scrub jays, pileated woodpeckers, wood storks, and gopher tortoises. I also hope to see the elusive, highly endangered Florida panther, and I look in hopes of seeing their tracks when outdoors. I go to the Myakka River State Park about 5 times a week, the Old Miakka Preserve about 2-3 times a month, and to the Peace River about 4-8 times a year – and I plan to continue doing so in the future.

37. All three of these recreation locations are in close proximity to citrus groves. There are areas of the Myakka River State Park, including the Myakka River, that are anywhere from a half-mile to up to three miles away from citrus groves. The Old Miakka Preserve is within a quarter mile of a citrus grove, and as discussed above, there are orange groves along several parts of the Peace River.

38. If streptomycin is sprayed at these groves, the aerosols could land in waterways and then flow to other parts of the park or preserve. And sheet flow could transport streptomycin residue from the soil into waterways when it rains. This could lead to increased exposure of the wildlife – including endangered species – that live in these areas, as well as to ECOSWF members who spend time in these locations.

Harms to Pollinators.

39. ECOSWF is also concerned about how streptomycin will affect pollinators. Abundant plants, sustained by pollinators, array the Myakka River State Park, Old Miakka Preserve, and southwest Florida as a whole.

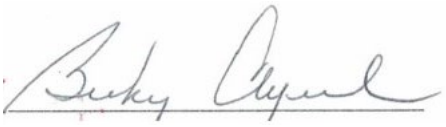
40. ECOSWF members and I are concerned that streptomycin will harm pollinators, and in turn, entire ecosystems of flowering plants that rely on them.

41. Florida is already at the epicenter of a biodiversity and environmental crisis and cannot sustain new environmental threats to people, wildlife, or our lands and waterways. Development and sprawl are rampant. Red tide and toxic algae blooms – for which agricultural

runoff is partly responsible – are causing fish kills and choking out marine life. In certain parts of the state, other agricultural practices like sugarcane burning are harming people's health. There are few remaining panthers in the wild, and manatees have been dying at record rates after losing federal endangered species protections. And earlier this year, the governor declared a state of emergency after a significant wastewater leak at the former phosphate mine Piney Point.

42. ECOSWF members cannot avoid exposure to antibiotics if streptomycin is sprayed near our homes and in our communities, near our drinking water sources, and near the wildlife we strive to protect. We *can* avoid another environmental catastrophe in Florida if this registration is vacated in its entirety, which is why we have joined this lawsuit. If the streptomycin registration is vacated, that would protect ECOSWF members and the species our organization works to protect from the threatened harms described in this declaration. I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed this 13th day of February, 2022, in Sarasota County, Florida.



Becky Ayech

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF MAURIE DUGGAN

I, Maurie Duggan, make the following declaration:

1. I am competent to make this declaration. I provide this declaration based upon my personal knowledge and experience. I would testify to the facts in this declaration under oath if called upon to do so.

2. I submit this declaration in support of the Environmental Confederation of Southwest Florida (ECOSWF), of which I am a member, in its legal challenge to the Environmental Protection Agency's (EPA's) approval of the use of streptomycin sulfate on citrus.

3. I am 65 years old, and I am from Sarasota County, Florida, where I have lived all my life. I am a longtime resident of the Old Miakka community, and I have lived here for the past 40 years. Old Miakka is a rural community of lush farmland and natural areas that support abundant vegetation and numerous livestock, bird species, and wildlife. The fertile agricultural lands of Old Miakka are just right for citrus farming operations. My family farm is surrounded by three of these groves.

4. I became a member of ECOSWF in the 1990s through my membership in the Old Miakka Community Club. I am drawn to ECOSWF's mission to protect the environment and my community from harmful contaminants used on farmland that can spread through the air and water and that may sicken people or animals. Application of pesticides, herbicides, fungicides, fertilizers, and other toxic substances pollute our air, our water, and the foods we consume, putting our health at risk. I am a member of ECOSWF because of the important work it does to protect against these harms.

5. I am aware of EPA's approved use of streptomycin for citrus canker and citrus greening, an approval ECOSWF has opposed since EPA first proposed it. The approval is of particular concern to me. My husband, daughter, son-in-law, grandson, and I live on a 5-acre pasture farm in close proximity to three citrus groves. Our entire property is within one to two miles of two of the orange groves, with the northeast boundary of our farm being only 0.5 miles as the crow flies from the first grove and the eastern boundary of our farm being one mile from the second grove. The western boundary of our property is five miles from the third grove.

6. I have an existing sensitivity to antibiotics and my family has a history of allergic reactions; I fear the same reactions from exposure to streptomycin. I have suffered allergic reactions to Sulfa antibiotic drugs that causes me to break out in rashes and hives and to become very flushed. My husband also has a propensity to allergic reactions; when he underwent an allergy test, his results showed that he was allergic to 298 out of 300 substances.

7. Many of our daily activities occur outdoors – on our property and in the community near citrus groves. Thus, if streptomycin is applied on these neighboring groves, we all risk exposure to streptomycin spray drift or residue, especially given our proximity to the groves. Additionally, our farming lifestyle involves taking care of our plants and animals, some of which we eat, which poses more sources of exposure to streptomycin.

8. For instance, we appreciate the opportunity to produce our own healthy and fresh foods at our farm. We grow fresh herbs and vegetables including zucchini, tomatoes, onions, green beans, chives, rosemary, and basil. I often use these vegetables and herbs while cooking. And we enjoy picking fruits from the lemon, key lime, mulberry, mango, and lychee nut trees on our property.

9. We also raise horses, chickens, cows, and pigs. Our animals roam our pastures freely. We currently have 10 chickens that provide our family with farm-fresh eggs for our meals. We have three horses that help us work the farm and maintain the grounds and that also participate in 4-H showings, an activity I participated in growing up and a tradition that I

passed on to my daughter. And we raise a cow and/or a pig as needed, which provides meat for our family.

10. I am worried about my and my family's direct exposure to streptomycin through the handling of our vegetables, fruit, and animals.

11. In terms of recreational activities, I frequently ride our horses and go on walks with my family along the dirt trails beside our farm. These dirt paths lead to a citrus grove. I also enjoy visiting our local vegetable market which is located at a nearby citrus grove 0.5 miles away.

12. When in our house, we keep the windows open for ventilation in the cooler months, from the end of October to the start of April.

13. These farming and recreational activities and the practices that are central to our lifestyle mean we are at increased risk of exposure to streptomycin spray or residue, increasing our risks of allergic reactions like rashes, hives, flushed skin, or other unknown health impacts.

14. Aside from my concerns about direct exposure to streptomycin, I am worried I could be infected by a superbug carrying antibiotic-resistant germs. Bacteria I am particularly concerned about becoming infected with

is Methicillin-resistant Staphylococcus aureus (MRSA), which is found in the soil and natural environment. MRSA is already resistant to the antibiotic Methicillin, and I worry it would become resistant to streptomycin as well from its use on citrus. Because I spend a lot of time outside gardening, tending to our animals, and doing maintenance and upkeep at the farm, I could have contact with antibiotic-resistant pathogens in the soil and natural environment, which could be spread by birds, insects, livestock, and wildlife that roam our property.

15. I am also anxious about potential exposure to antibiotic-resistant bacteria via contaminated food sources, since we regularly consume beef, pork, vegetables, fruits, and eggs produced on our farm.

16. I worry that my family and my lifestyle will be drastically impacted by exposure to streptomycin and to antibiotic-resistant bacteria, since we rely on our farm as a major source of our food, and our farming lifestyle requires us to spend a significant amount of time outdoors. I also worry we will not be able to enjoy the pleasures of living in Old Miakka because of potential exposure to streptomycin and to antibiotic-resistant

bacteria, possibly forcing us to avoid the activities we enjoy, such as riding our horses or going to the nearby market.

17. Exposure to streptomycin or to antibiotic-resistant bacteria from our water is also of great concern to me. Old Miakka experiences heavy rainfall and our farm is the drain field area from where groves are located. I fear that runoff from rain could carry streptomycin residue and antibiotic-resistant bacteria from the citrus grove to my property, getting into our ponds and thriving there.

18. Furthermore, we have a private groundwater well at our farm that is our sole source of water: this is our drinking water, tap water, and shower water, and it would be detrimental if it became contaminated. Among other adverse effects, we could suffer allergic reactions from drinking our water or being exposed to streptomycin residue when we shower, and our water supply and property could become a breeding ground for antibiotic-resistant pathogens.

19. As a 65-year-old, diabetic, overweight woman, I am immunocompromised. I am very concerned that if I become sick from

antibiotic-resistant bacteria, I will either not successfully respond to treatment – placing my life at risk – or will have to take stronger doses or types of antibiotics, which could have dangerous side-effects.

20. I am equally additionally afraid of the possible consequences streptomycin exposure could have on my gut health. I am very careful about maintaining my gut health, since we do not get the nutrients directly from the foods we eat, but rather, we obtain our nutrients from the microbes in our guts that help us digest our foods. Streptomycin may alter the microbiology in my gut and kill the good bacteria that helps me digest food.

21. I am also deeply concerned about the impact streptomycin spraying could have on pollinators. Pollinators, especially birds, bees, and butterflies, are instrumental to the health of my vegetable garden and fruit trees. I am fearful that streptomycin will be toxic to pollinators, who could be exposed to the antibiotic through the air, water, or their food sources. If streptomycin harms pollinators, my garden will suffer, and I will miss out

on the peaceful and treasured experience of going into my garden to watch birds, bees, and butterflies.

22. Streptomycin may also affect our honeybees and honey production by contaminating the honey harvested locally. As a diabetic, I eat a lot of honey, as it serves as a natural sweetener alternative. I particularly enjoy orange blossom honey, and potential exposure to streptomycin will limit my sources of nutrition as a diabetic.

23. Additionally, I am deeply concerned for the wildlife that call Myakka River State Park and the Old Miakka Preserve home. These natural areas are near citrus groves. My family and I frequent these natural areas to observe wildlife and enjoy the outdoors. I am anxious about how streptomycin may affect the animals' gut bacteria and that different species may die off as their habitats become polluted with the antibiotics or resistant pathogens.

24. I am particularly concerned for the Florida panther, classified as an endangered species under the federal Endangered Species Act. The comeback of the Florida panther has been tenuous; I am always on the

lookout for panther prints while trail riding and I hope to see a panther one day. But I fear that the panther population may continue to be destroyed with the use of streptomycin near their habitat.

25. Streptomycin application on citrus groves should be prohibited. EPA's approval of the use of streptomycin on citrus puts me and my family's health at great risk, while also risking harm to pollinators and to federally protected wildlife in Old Miakka and beyond. To avoid these risks, the court should vacate this registration, and EPA should instead look for a solution to citrus canker and citrus greening that does not infringe on the health and safety of people, wildlife, the environment, and our quality of life.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed this 14th day of February, 2022, in Sarasota County, Florida.

Maurie Duggan

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF TRENT TAYLOR

I, Trent Taylor, do hereby affirm and state:

1. I am a staff attorney at Farmworker Justice. I am responsible for supervising and overseeing all litigation and supervising junior attorneys. Prior to joining Farmworker Justice, I represented low-income Latino workers, including farmworkers, in union representation and wage and hour law matters. I feel passionately about farmworker issues and am committed to protecting farmworkers from the myriad health harms that they suffer in the workplace.

2. Farmworker Justice is a national nonprofit organization dedicated to empowering migrant and seasonal farmworkers. Agricultural labor is one of the most hazardous occupations in the nation. This is in part because farmworkers have historically been excluded from a wealth of labor and health protections. Farmworker Justice aims to step into the breach to partner with and advocate for farmworkers.

3. Our mission is to improve health, occupational safety, living and working conditions, immigration status, and access to justice for farmworkers. To accomplish its goals, Farmworker Justice engages in capacity-building assistance, health promotion, leadership development, public education, advocacy, litigation, administrative monitoring, and coalition building.

4. More than 20 percent of the farmworkers we work with are engaged with work in citrus crop cultivation and harvesting at various times of the year.

5. As part of our mission to improve farmworkers' living and working conditions, we advocate for measures to limit workers' pesticide

exposure, including, but not limited to, improving worker protection regulations, addressing pesticide drift, banning highly toxic pesticides, and educating workers on the health impacts of pesticides.

6. Farmworker Justice educates the public, lawmakers, and government officials about the dangers of pesticide exposure for farmworkers and their families, and the need to reduce agricultural pesticide use. Farmworker Justice has connected with hundreds of farmworkers and dozens of community-based organizations across America to help workers and their families gain greater awareness of such occupational hazards and to guard against pesticide-related health harms.

7. We produce several educational materials for farmworkers including issue briefs, guides, illustrated brochures, and factsheets. These resources and training materials related to pesticides include summaries of the federal Worker Protection Standard and "train the trainer" curricula for pesticide safety training. We also maintain a Health Policy Bulletin to share information with the public on policy developments and academic research impacting farmworker health.

8. Farmworker Justice often contracts with community partners to provide educational resources to farmworker communities. We work with community outreach groups, health organizations, and farmworker labor groups to provide on-the-ground trainings and presentations to educate farmworkers and their communities about pesticide exposure and safety precautions.

9. To compensate these outreach, health, and labor groups for their educational and training efforts, we subcontract grant funds given to Farmworker Justice.

10. EPA's registration of streptomycin for use on citrus crops is deeply concerning to Farmworker Justice. We are concerned about toxicity from direct contact with streptomycin residue, as well as the resulting spread of antibiotic resistance in both bacteria exposed to streptomycin and bacteria broadly. We are confident that EPA's decision will lead to an increasing number of farmworkers and their families suffering from antibiotic resistant diseases. EPA's harmful action therefore frustrates Farmworker Justice's mission to promote the health and safety of

farmworkers, and to ensure that the law adequately protects farmworkers from hazardous working conditions, including exposure to dangerous toxins and disease.

11. Because of these concerns, in March 2019, Farmworker Justice joined a coalition of organizations to submit public comments to EPA opposing the agency's registration of streptomycin for use citrus crops. Our comments discussed substantial evidence that such an action by EPA would result in unreasonable adverse effects to human health and the environment, in violation of federal law.

12. We understand that pesticides can be important to the cultivation of crops in the U.S. But we are also very aware of the serious health harms that these pesticides represent for farmworkers and their families. The approval of a pesticide such as streptomycin – which has limited or no positive effect on the cultivation of crops, but which creates tremendous dangers imperiling farmworker health — is something Farmworker Justice will continue to fight as a top-tier organizational priority.

13. My colleagues and I are familiar with the punishing working conditions of citrus grove workers — conditions that increase such workers' vulnerability to disease and poor health outcomes. Farmworkers involved in the harvest and cultivation of citrus crops work very long hours — they normally start at daybreak and continue until sunset for six or seven days are week. Many do not have breaks, even for lunch, and are forced to comply with onerous standards requiring them to pick a specified number of baskets of citrus fruits per day. Citrus farmworkers often have deplorable living conditions as well, sometimes with several workers inhabiting a single trailer with just one bathroom and stove. Some workers do not have consistent running water or electricity or access to first aid.

14. We hear reports that workers are not always provided the personal protective equipment (PPE) they need from their employer, or that the PPE provided may be defective— such equipment may be expired, broken, already used, or impaired in other ways.

15. Workers also often wear the same clothes and shoes they use in the field at home, contributing to pesticide residue transfer.

16. As a result of EPA's dangerous decision to permit the widespread use of the antibiotic streptomycin on citrus crops, Farmworker Justice will be injured, and its resources will be diverted from other important work.

17. Streptomycin represents the first agricultural antibiotic that Farmworker Justice has worked on, so its approval will compel us to create new materials and considerably augment our institutional knowledge about agricultural antibiotics and antibiotic resistant diseases. Because of EPA's registration, we will newly dedicate substantial resources – financial and staff time – to investigating, researching, and disseminating information to farmworkers, the federal government, states, and the public on streptomycin toxicity and the spread of antibiotic resistant disease in farmworker communities. We will publish our findings in various fora including our Health Policy Bulletin and share them with farmworkers, lawmakers, and agency staff.

18. In addition, as a result of this registration, Farmworker Justice will also expend time and resources to create and publish new materials

such as issues briefs, illustrations, and guides, explaining the harms that can stem from exposure to streptomycin and from the spread of antibiotic resistant diseases. We will conduct new, dedicated outreach to community-based organizations and farmworkers to disseminate information on streptomycin and antibiotic resistant illnesses.

19. EPA's registration will additionally compel Farmworker Justice to newly dedicate sizeable portions of our grant funds to subcontracting with health organizations and farmworker labor groups to provide targeted trainings around issues pertaining to antibiotics in agriculture and antibiotic resistant illnesses. Relatedly, we will spend time and money to incorporate information on streptomycin and antibiotic resistance in our 'train the trainer' curricula for pesticides safety training.

20. Farmworker Justice has litigated numerous cases related to pesticide exposure in order to protect farmworkers. For example, Farmworker Justice is currently counsel in litigation challenging EPA's weakening of protections in the national Agricultural Worker Protection Standard. Representing several farmworker and pesticides-advocacy

groups, Farmworker Justice also sued to compel EPA to set safety standards protecting children from health harms emanating from pesticide drift from farms in 2014. We were also a party in litigation challenging EPA's approval of the use of the dangerous pesticide chlorpyrifos, and our staff members testified and conducted regulatory advocacy across the country in favor of banning its continued use.

21. If EPA were to reverse its decision to register streptomycin, Farmworker Justice would no longer have to expend resources to urge EPA to better protect farmworkers on this issue and to educate farmworkers, the public, lawmakers, and agency staff on the dangers of massively expanding agricultural streptomycin use. Because Farmworker Justice is already involved in many campaigns and litigation efforts to limit the use of particular pesticides, taking one pesticide off the list would relieve the organization from substantial resource commitments and allow budgetary and staff resources to be redirected to important existing projects.

22. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

SIGNED: December 17, 2021, in St. Louis, Missouri.

Trent Taylor

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF JEANNIE ECONOMOS

I, Jeannie Economos, make the following declaration:

1. I am the Pesticide Safety and Environmental Health Project Coordinator for the Farmworker Association of Florida (FWAF), a grassroots, nonprofit organization that fights for equity, justice, and better living and working conditions for farmworkers and rural, low-income communities of color and their families.

2. I am competent to make this declaration. I submit this declaration based upon my personal knowledge and my years of

experience as a pesticide health and safety advocate for farmworkers and their families. I would testify to the facts in this declaration under oath if called upon to do so. I submit this declaration in support of the legal challenge, in which FWAF is a Petitioner, to the Environmental Protection Agency's (EPA's) unconditional registration of the use of streptomycin sulfate on citrus.

3. I reside in Orlando, Florida. I work in Apopka, Florida, where FWAF's headquarters are located. Apopka is just north of Orlando and calls itself the Indoor Foliage Capital of the World because it produces many ornamental and foliage plants.

4. FWAF was founded in 1983 and incorporated in 1986, to uphold the dignity, worth, and value of farmworkers and low-income, rural communities and to build their power with respect to the social and environmental justice issues that impact their lives. Our work involves farmworkers' occupational health and safety, which includes trainings on remaining safe and protected from pesticides and heat stress; advocacy efforts surrounding pesticide and heat safety; and aid to workers who have

been victims of wage theft, workplace discrimination, and labor trafficking. We also provide disaster relief and immigrants' rights education, assistance, training, and advocacy.

5. Throughout the state of Florida, there are over 10,000 members of FWAF, comprised of farmworkers, rural community members, low-wage immigrant workers, and those concerned for the rights and wellbeing of members of these communities. An individual becomes a member by paying annual dues of $20 and obtaining a membership card.

6. FWAF's mission, however, extends beyond its membership. As an organization, we work for the health, safety, rights, and protection of *all* farmworkers in Florida – one of the most vulnerable groups of people in our society. Many farmworkers are migrant or seasonal workers from Mexico, Central America and the Caribbean who have temporary or no legal immigration status, placing their employers in a unique position of power over them. This dynamic means many farmworkers are afraid to organize or speak up out of fear of retaliation or deportation. Due to these fears, farmworkers may not report workplace violations or discrimination;

however, this does not mean they are not adversely impacted by occupational health risks and environmental hazards at work. Understanding these realities of the agricultural industry, FWAF's mission is to lift up the voices of and advocate for all farmworkers.

7. Our mission of being a community-based organization that advocates for the rights and protections of all farmworkers across all agricultural industries, even if they are not FWAF members, provides protections to our members as well: if the government lowers the standards for farmworkers in one industry (for example, here, the citrus industry), it sets a precedent of lowering protections across other agricultural industries.

8. To carry out its mission, FWAF is led and governed by members who make up local leadership committees at each of our five area offices around the state. With the facilitation of FWAF's staff, the committees are the driving force carrying out our mission through programming, events, trainings, activities, and discussions. Every four to five years, FWAF holds a general assembly where members elect a new

Board of Directors and strategically identifies the priority issues on which the organization will focus. We also rely on members to volunteer in a more direct service capacity, to do such things as distribute food or clothing to farmworkers, as examples.

9. Since its inception, FWAF has been working on pesticide health and safety issues impacting farmworkers. FWAF has been conducting pesticide trainings for farmworkers since 1995, when EPA implemented the first Worker Protection Standards for agricultural workers.

10. Between 1995 and 2007, I was involved with FWAF as either a volunteer or full-time employee. Since 2007, I have been the Pesticide Safety and Environmental Health Project Coordinator for the organization. My job duties over the years have included, in relevant part, coordinating and carrying out health and safety trainings for farmworkers as it relates to pesticides, updating these trainings and materials over time, filing complaints for workplace violations, training healthcare providers at local clinics about pesticide poisoning as it relates to farmworkers, and advocating for stronger health and safety protections for farmworkers.

11. Currently, I engage in community-based research projects on farmworker health, including on pesticide risks and exposure, with partner universities such as Emory University, Florida State University, and the University of Florida. I organize efforts for farmworkers to advocate on their own behalf before EPA's National Environmental Justice Advisory Council and to policy makers and regulatory bodies. And I engage in litigation efforts on behalf of FWAF (such as this case) and enforcement work (such as monitoring for violations of worker protection standards and reporting them to relevant state and federal agencies).

12. At the proposed rule stage, FWAF strongly opposed EPA's plans to approve the new use of streptomycin at issue in this case. We, along with a coalition of other farmworker justice and environmental groups, submitted comments to EPA discussing the health risks that the use of streptomycin on citrus could cause; the deficiencies in EPA's health risk assessment; and the realities of agricultural work, as it relates to the use of personal protective equipment (PPE), that EPA failed to consider.

13. FWAF and its members remain opposed to this new use of streptomycin: using farmworkers as guinea pigs for a pesticide that can harm their health, based on an inadequate and incomplete health risk assessment, is unacceptable.

14. As we noted in our comments to EPA, exposure to streptomycin can cause health risks such as skin and eye irritations and harms to the kidneys and inner ear. These health risks exist from the therapeutic use of streptomycin as a drug; it follows that these risks will increase significantly from the application of larger quantities of streptomycin via air blast spray, over an extended period.

15. Furthermore, FWAF and its members are concerned about the cumulative, synergistic, and additive health impacts on its farmworker members' from their exposure to streptomycin over time. Specifically, we are concerned about health harms from streptomycin bioaccumulating in farmworkers' bodies (cumulative impacts), interacting chemically with other pesticides to which farmworkers are exposed (synergistic impacts),

and increasing the overall health harms to farmworkers when added to impacts from exposure to other pesticides (additive impacts).

16. FWAF and its members are also deeply concerned about growing antibiotic resistance stemming from EPA's approval of this registration. Antibiotic resistance – which causes otherwise treatable illnesses to become life-threatening because antibiotics are no longer effective at treating them– is an ever-increasing public health crisis. According to the Centers for Disease Control (CDC), we are no longer *approaching* a "post-antibiotic era," but rather, we are already there. The latest CDC statistics show that antibiotic-resistant bacteria infect more than 2.8 million people in the United States each year and kill more than 35,000 people as a result.[1]

17. FWAF and its members are also worried about how each of these risks – direct harmful reactions to streptomycin spray; cumulative, synergistic, and additive impacts in members' bodies over time; and the

[1] CDC, "Antibiotic Resistance Threats in the United States," at vi, vii, https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf (2019)

prevalence of antibiotic-resistant bacteria – will particularly impact pregnant members, members who are women of reproductive age, and the developing fetus.

18. FWAF is deeply concerned that its members will face an increased risk of health harms that would otherwise not exist if EPA had not approved this use of streptomycin. While people can generally exercise control over their consumption of and exposure to antibiotics, the air blast spraying of streptomycin onto citrus crops makes exposure to streptomycin and antibiotic-resistant bacteria unavoidable for FWAF members who work in, live near, or otherwise have reason to be near a citrus grove.

19. EPA's assumptions that the use of personal protective equipment (PPE) will alleviate any risk of exposure to streptomycin are not supported. EPA provided no assurance that the PPE this registration requires would mitigate or remove health risks from exposure to antibiotics.

20. EPA also ignored the realities of PPE use among agricultural workers, assuming without evidence that farmworkers will wear the PPE

included as part of the registration. But that is not realistic. It is not simply a matter of farmworkers refusing to wear PPE; rather, it may not be safe or feasible for farmworkers to wear it, or they may not have access to it.

21. In Florida especially, heat (and extreme heat) is a climate change threat that FWAF has studied and works to protect its members from. The heavy PPE that EPA requires as part of this registration – protective eyewear, coveralls over a shirt and pants, gloves, socks with shoes, and a respirator – would increase a farmworker's core body temperature in an already hot setting. Even without PPE, farmworkers are exposed to heat-related illnesses such as dehydration, heat stroke, and acute and long-term kidney damage. And climate change projections predict hotter days and increasing temperatures, with areas of Florida on track by 2030 to see temperatures over 105 degrees Fahrenheit for 114 to 150 days a year. Heat, coupled with the fact that workers are often not paid hourly, but rather, by "piece rate" (i.e., a fixed rate for a container of a crop harvested), means there is an incentive to work faster over longer hours and not take breaks to cool off and drink water. Given these realities,

farmworkers may not wear the heavy PPE that EPA requires as part of this registration because they would overheat.

22. Additionally, employers often do not provide PPE to their workers, so it is not fair to assume that farmworkers have access to PPE.

23. FWAF and its members are opposed to the use of streptomycin on citrus because of the significant health risks it poses to farmworkers and their families. FWAF supports this lawsuit to vacate this registration and instead look for alternative, effective ways to control citrus diseases that are safe for the essential workers who sustain our food system and for community members near citrus groves. A court order vacating this registration would alleviate FWAF and its members' significant concerns about the use of streptomycin on citrus.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed this 16th day of February, 2022, in Orlando, Florida.

Jeannie Economos

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF ANTONIO TOVAR

I, Antonio Tovar, make the following declaration:

1. I am competent to make this declaration. I provide this declaration based upon my personal and professional knowledge and experience. I would testify to the facts in this declaration under oath if called upon to do so.

2. I am a member of Farmworker Association of Florida (FWAF), and I submit this declaration in support of FWAF's legal challenge to the

Environmental Protection Agency's (EPA's) approval of the use of streptomycin sulfate on citrus.

3. I am 53 years old and recently moved to Washington, D.C. from Florida. I have a Ph.D. in medical anthropology and a master's degree in cultural anthropology, both from the University of Florida. I also have a bachelor's degree in philosophy from the Universidad de Guanajuato in Mexico.

4. I currently work as a policy associate with the National Family Farm Coalition (NFFC) in Washington, D.C., which is an alliance of farmer, rancher, and fisher organizations that has a presence in 42 States, including Florida. As a policy associate, I am currently involved in two research projects on issues of heat stress and pesticide exposure prevention as it relates to farmworkers.

5. I have been a member of FWAF for the past 15 years, and I was also a paid employee of the organization for 17 years, up until September 2021. I became a member because I value the organization's work disseminating information to help the farmworker community. The

"piece-rate" wage system – where workers are paid by how much they harvest rather than hourly – means farmworkers will labor as long and as fast as they can to earn enough money to feed their families. This means they often do not have the time or resources to also educate themselves about the threats from their work. I joined FWAF because I wanted to contribute to its mission of developing resources to educate and train farmworkers on the issues that impact them. It is a mission that has always resonated with me because my family members in Mexico used to be farmers.

6. I have held several roles in FWAF over the years: I served for two years as the executive director, I led various research projects, and I have carried out administrative duties for the organization. At FWAF, I led and conducted research on issues related to farmworker health and safety, which includes issues like pesticide safety, heat stress, and workers' mental health. I worked alongside universities and other nonprofits to carry out studies and publish findings, working closely with impacted farmworkers

to collect data. I also wrote policy proposals on behalf of FWAF on pressing issues affecting farmworkers.

7. Several years ago, I led FWAF's involvement in the Partnership for Citrus Worker Health with the University of South Florida. Through this collaboration, we identified health issues affecting farmworkers and developed trainings and resources to help them protect themselves. For instance, eye injuries are common among citrus workers due to a variety of environmental factors, so one such training focused on the importance of wearing safety glasses.

8. In collaboration with harvesting companies, I still carry out trainings like these in Florida during the citrus season.[1]

9. Farmworkers often do not have their own transportation, so when I conduct trainings, I travel to them. Trainings typically take place at their homes, which are often right next to the citrus groves where they work. The trainings are not one-off events either; I will carry out multiple trainings at each of the various locations where I travel to citrus workers.

[1] In Florida, the citrus season typically runs from October to June.

10. Aside from trainings, I also have many friends in the farmworker and research community in Florida who live near citrus groves, with whom I visit when I am in Florida. If I had to estimate, I would say I travel to Florida approximately monthly and visit with friends who live near citrus groves, and I plan to continue doing so. For instance, I have plans to travel this month to Sebring, Florida to visit a research colleague who lives next door to a grove.

11. Through my involvement in FWAF, I am aware of the government's approval of the use of streptomycin to treat citrus greening and citrus canker. I am opposed to this use of streptomycin not only because of the health risks it poses to workers, but also because I am often near citrus groves during the citrus season, and this could place my own health at risk.

12. Prior to this case, I was already mindful of antibiotic resistance and the potential harms from the overuse of antibiotics. For instance, I make a point to eat antibiotic-free meat to avoid unnecessary consumption of antibiotics. I am therefore worried that I could experience an allergic

reaction or become infected by antibiotic-resistant bacteria from carrying out trainings near citrus groves.

13. I am concerned I could be exposed to streptomycin through a variety of ways when conducting health and safety trainings or when visiting friends who live near citrus groves. First, spray drift can settle into the soil on the properties I visit, and I could then carry this drift on my shoes and into my car and the place I am staying afterwards. Second, streptomycin residue could settle on exterior surfaces of homes that I visit near groves that I could come into contact with. Third, inside citrus workers' or friends' homes, I could be exposed to streptomycin residue that was carried inside on their clothing and shoes.

14. Moreover, what do citrus workers offer me when I visit? Oranges. They also offer me tap water to drink. I am concerned both the fruit and the water could be contaminated with streptomycin. Yet I would be rude to refuse their offer of food and drink.

15. I also fear that the overuse of antibiotics will cause a rise in antibiotic-resistant superbugs, and citrus workers' and friends' homes and

surrounding areas could become hotspots for antibiotic-resistant bacteria. Personally, I am worried that I could carry antibiotic-resistant bacteria from homes near groves that I visit to the hotel or other places I stay when visiting Florida, placing me at a higher risk for infection.

16. I have sleep apnea, a condition in which the throat relaxes and blocks a person's airways intermittently while sleeping. As a result, I must use a continuous positive airway pressure (CPAP) machine, which delivers oxygen though a ventilator mask worn over my nose. I am worried that antibiotic-resistant bacteria will enter the ventilator mask, which I wear for several hours at a time when sleeping to help me breathe, increasing my chances of becoming ill.

17. From everything I have read, we are moving into a post-antibiotic world where strains of resistant bacteria could unleash public health crises on the scale that we have seen with the Covid-19 pandemic. I do not want to live in a world where I and others could become ill and risk dying from infections that cannot be treated with antibiotics. This

unnecessary use of streptomycin on citrus contributes to this public health problem.

18. There are far too many unknowns as to how this approved use of streptomycin could impact human health. Instead of attempting a quick fix for citrus illnesses, the government should develop long-term solutions that do not place my, my family, the farmworker community, and the general public's health at risk.

19. I support FWAF's participation in this lawsuit because of the potential health threats to myself, my family, and to farmworkers if this registration is allowed to remain. If the court were to vacate this registration, that would alleviate the fears and concerns that I have, discussed in this declaration.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed this 16th day of February, 2022, in Washington, D.C.

Antonio Tovar

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF JEAN MCCOLLOM

I, Jean McCollom, do hereby affirm and state:

1. I am a member of the Natural Resources Defense Council.

2. My husband and I have been members of NRDC for about 15 years because we are very concerned about wildlife and plants, and we support NRDC's work to protect wildlife and plants.

3. I have lived in Naples, Florida, since 1981. I live down the street from the Corkscrew Swamp Sanctuary. My home is also one-third of a mile from citrus groves.

4. I am an ecologist and biologist by training. I have a master's degree in watershed management from the University of Arizona's School of Natural Resources.

5. My primary work has been on natural ecosystems management and restoration in Florida, although when I was with Audubon I worked around the country. After a career working for the National Audubon Society, the Nature Conservancy, and the Florida Fish and Wildlife Conservation Commission, I am now retired.

6. I am still active as a volunteer in natural areas, including on plant surveys, as a member of a prescribed-burn team in the Corkscrew Swamp Sanctuary, and as a member of the Florida Invasive Species Council committee that identifies exotic plants to be listed as a problem for natural areas. I also continue to participate in and publish ecological research.

7. Much of my professional and volunteer work has been in Corkscrew Swamp Sanctuary, Okaloacoochee Slough Wildlife

Management Area, and the Disney Wilderness Preserve, all of which are surrounded by citrus groves.

8. In my current volunteering at Corkscrew Swamp Sanctuary, we monitor marsh restoration which involves the elimination of encroaching willows, then maintain the marshes using prescribed fire.

9. I understand that EPA has recently approved the antibiotic streptomycin for use on citrus crops, including in Florida.

10. I am concerned about the use of streptomycin on citrus crops both near my home and near natural areas that I frequently visit. I believe that streptomycin use could affect both wildlife and people.

11. In my ecosystem restoration projects, I have used a lot of herbicide. As a result, I am aware of how chemical treatments can lose their effectiveness and cause major problems as the organisms they target develop resistance over time. I have seen a similar thing happen with glyphosate, and understand that it can happen with antibiotics too.

12. If bacteria mutate to respond to the mass sprayings of streptomycin, it becomes increasingly likely that the antibiotic will no longer work well on people, and it could introduce more stress to wildlife.

13. I am always outside looking at wildlife. I have wildlife cameras in my yard because I find it really interesting to see what goes through where you were just walking; I enjoy looking at and keeping track of the animals on our five-acre wooded lot.

14. Using these wildlife cameras, I have recorded dozens of pictures of endangered Florida panthers as well as other species including deer. The deer eat the vegetation in our lot and the panthers eat the deer in turn. I have included two of these pictures of panthers below.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15. In addition to seeing panthers using the wildlife cameras on my property, I have also seen endangered Florida panthers in the wild. You don't see them in person very often, but it is very impressive when you do. It's an incredible thrill to see them in the wild. Seeing a Florida panther gives me a sense of euphoria, and I am always so excited to see one because they are so rare. I hope to have the experience of seeing a Florida panther in the wild again.

16. Florida panthers go through the nearby Corkscrew Swamp Sanctuary, where I regularly visit and volunteer. I have seen panthers in Corkscrew while running there with my dog. I have included pictures I have taken of a Corkscrew Swamp wetland and endangered wood storks nesting below.

17. When I worked for Florida Fish and Wildlife, I once released a captive panther into the wild. I could hear it growl when we released it, and I will never forget that memory. I also have strong memories from when I participated in the capture and radio-collaring of a panther.

18. I am concerned about the number of threats to Florida panthers. One concern I have is over a mysterious disease that causes the back legs of Florida panthers to be paralyzed. The cause of this disease is

unknown, although one possibility is that it is caused by bacteria. Introducing streptomycin to the panthers' habitat would be adding yet another stressor, thereby decreasing the ability of these already vulnerable creatures to survive and reproduce.

19. If streptomycin affects insects, it will also affect the endangered Florida bonneted bat—another species in which I have a keen interest. There is very little data on this Florida species, but it has been documented in groves and many neighboring natural and human habitats. It is hard to protect these bats without much information.

20. I have seen Florida bonneted bats leave their roost in a pine tree in Big Cypress National Preserve. On that occasion, I went out to help count the bats that night with a biologist. We videoed them leaving the tree at dusk and recorded the bats' calls by using sound devices that capture their echolocation calls.

21. I have also participated in bat surveys and netting in Picayune Stand State Forest and in the Okaloacoochee Slough Wildlife Management Area and State Forest.

22. In addition, there are nesting boxes for the Florida bonneted bat in the Babcock/Webb Wildlife Management Area. I have not seen them there yet, but I have collected seeds in that area and hope to see them there on future visits.

23. It is exciting to spot Florida bonneted bats because they are so rare. Although I would like to see these bats again, I do not know when I will be able to because there are so few of them left. However, I plan to continue to try and see the bats again.

24. I am also concerned about the endangered wood stork which comes to southwest Florida in the winter to live and nest. They feed on fish and can travel long distances for food in wetlands which can be near, adjacent to, or in citrus groves.

25. I see wood storks regularly flying over when I am out, and these large birds are a sight to see. In a typical year often 100,000 people, including me, go to Corkscrew Swamp Sanctuary just down the street from my home where wood stork watching is a common attraction.

26. For endangered species including the Florida panther, wood stork, and Florida bonneted bat, one possible avenue for exposure to streptomycin that I am concerned about is through wetlands. Water in wetlands houses plants and animals that are the base of the food chain for a lot of animals; many animals also need to drink water to survive. If streptomycin gets in water, which I expect it will, it could directly or indirectly harm many animals.

27. Florida regulates the water used in citrus groves. During the summer, growers have to pump the water out if the depth exceeds a certain level or it will kill the citrus trees. That water then goes into wetlands downstream where it spreads and flows across the landscape as a thin sheet of water and also creeps into the groundwater. During the winter, growers have to pump groundwater into the fields to water the trees. Anything that is sprayed on the trees is also getting into the water. Florida is a very porous system made of sand and limestone, and water moves through it very easily. There is a lot of citrus in the area, so anything that gets in the water will be spread in a number of directions.

28. I am also concerned about the effects that streptomycin use will have on good bacteria in soil. These bacteria are integral parts of ecosystems that we do not want to lose. The use of streptomycin could be disastrous on a microbial level that would affect plants, animals, and people. Spraying antibiotics over such a broad area will have effects on things other than citrus, and I worry that so little is known about the good bacteria in soil and how this antibiotic use could disrupt ecosystem functions—including in the ecosystems that I visit and volunteer in.

29. If streptomycin is sprayed on citrus, I am concerned that I will be directly affected by it because I regularly walk near citrus groves.

30. I worry about the impacts of spraying streptomycin on citrus near me, especially since I am next door to Corkscrew Swamp Sanctuary. Collateral exposure is probably going to happen, as streptomycin moves out of groves and into surrounding areas.

31. I also worry that streptomycin has not been stringently tested. We know that local harmful bacteria can become insensitive to antibiotics, and I am concerned about that happening. It's common sense that this use

is not something that we should be doing, particularly when we may have alternatives in this country. I think that without a shadow of a doubt this use of streptomycin will result in increased antibiotic resistance, and that it might no longer be effective for people, including me.

32. I also have concerns that this use of streptomycin will not work after reading a study from the University of Florida. Citrus leaves have a thick, waxy outer layer, so very little would actually get through that layer to the plants. I also read the letter from Senator Elizabeth Warren and Representative Jackie Speier to the EPA about a need for more research on streptomycin and saw that the Centers for Disease Control and the Food and Drug Administration both raised objections to this use of streptomycin. We certainly don't need to use streptomycin in this way if it is not helping.

33. I worry that the approval of streptomycin for use on citrus crops will impact plants and wildlife in the natural areas that I regularly visit and volunteer in. I am also concerned about direct effects to me because I live near and often walk past citrus groves. If streptomycin is

used on citrus crops, I believe it could harm endangered species like the endangered Florida panther, wood stork, and Florida bonneted bat that I enjoy seeing in the wild. I also worry about broader impacts to ecosystems through streptomycin's spread in water, including to soil microbial communities and wetland invertebrates and fish, that would harm the areas like Corkscrew Swamp Sanctuary where I work on ecosystem restoration projects.

34. I believe that revoking the registration of streptomycin under the Federal Insecticide, Fungicide, and Rodenticide Act and requiring the Environmental Protection Agency to analyze the effects of streptomycin's registration on threatened and endangered species under the Endangered Species Act will protect the plants, wildlife, and ecosystems that I care about and that I visit and volunteer in. I therefore support NRDC's petition challenging the federal government's approval of streptomycin.

35. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

DATED: February 20, 2022

Naples, FL

Respectfully submitted,

_/s/Jean McCollom_____

Jean McCollom

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF SARAH GORDON

I, Sarah Gordon, do hereby affirm and state:

1. I am a member of the Natural Resources Defense Council.

2. I have been a member of NRDC for over 20 years. I am a member because I am concerned about and committed to the protection of the environment for humans and species that inhabit the earth.

3. I have lived in Oceanside, California, for over 33 years.

4. I am aware that antibiotic resistance poses risks to people, and I believe that the registration of streptomycin for use on crops is

irresponsible. Before the registration of streptomycin, I was unaware of any use of antibiotics on food crops.

5. I have a structural lung condition called bronchiectasis. This condition involves development of malformed channels in the tiniest branches of the lung, which get misshapen and can't expel fluids easily. The structural condition makes me prone to having bacteria grow in my lungs, including mycobacterium avium complex (MAC).

6. MAC is difficult to treat. If it worsens, I will need a three-drug regimen that would involve either streptomycin or another related antibiotic, azithromycin.

7. Although I have not yet had to use streptomycin, my pulmonologist and I believe that I may need to take it for treatment. I have been seeing my pulmonologist for years. Over a year ago, I began to have a worsening of symptoms. My pulmonologist discovered the particular MAC cluster through a CT scan and a description of the symptoms that led to further testing. As a result, my pulmonologist explained that I might have to take a three-drug regimen with streptomycin or azithromycin as an

antibiotic. The treatment would last for about a year. My symptoms improved so we decided against it, but I recently had another CT scan to look for similar symptoms. If my condition worsens, I want to be able to use those antibiotics.

8. It is a matter of life and death for me to be able to use streptomycin or the related antibiotic azithromycin.

9. The bacteria associated with MAC are well known to become antibiotic resistant quickly. Resistance to either streptomycin or azithromycin could also indicate resistance to the other antibiotic.

10. If bacteria become resistant to an antibiotic treatment regimen, then doctors will likely prescribe different antibiotics. However, those options might not be as effective.

11. There are large citrus groves within about 20 miles of my home and smaller groves within about 12 miles. I drive past them for various reasons, and I love the incredible smell from the citrus blossoms that permeates the air.

12. I drive through commercial citrus groves on my way to Ramona, an area that my husband and I go to about three to four times a year for weekend stays or retreats. We are both trained teachers of Transcendental Meditation, and we teach retreats at a facility in Ramona. We also visit friends there outside of teaching courses. Although we have not led any courses there during COVID, we plan to do so again after the pandemic eases.

13. I am concerned that I could breathe in streptomycin directly while driving by citrus groves, which could cause resistance to it to develop in bacteria already in my lungs.

14. I worry that the approval of streptomycin for use on citrus crops will result in bacteria becoming resistant to the antibiotic. I also worry that I will be exposed to such streptomycin-resistant bacteria because my travel to Ramona regularly brings me near citrus groves where streptomycin can now be used. If streptomycin-resistant bacteria grow within my lungs, this would make my lung condition more difficult to treat and result in potentially life-threatening harms to my personal health.

15. I believe that revoking the Environmental Protection Agency's approval of streptomycin would prevent the use of streptomycin on citrus—including the citrus groves near me—and therefore reduce my chances of coming into contact with this antibiotic and thereby developing drug resistance to streptomycin, azithromycin and other antibiotics in the same class, or of being exposed to harmful bacteria that become resistant to streptomycin. I therefore support NRDC's petition challenging the federal government's approval of streptomycin under the Federal Insecticide, Fungicide, and Rodenticide Act.

16. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

DATED: February 22, 2022

Oceanside, California

Respectfully submitted,

/s/ Sarah Gordon

Sarah Gordon

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF GINA TRUJILLO

I, Gina Trujillo, do hereby affirm and state:

1. My name is Gina Trujillo. I have personal knowledge of the matters stated herein.

2. I am the Director of Membership for the Natural Resources Defense Council (NRDC). I have been employed at NRDC for thirty years. My duties as Director of Membership include supervising the maintenance

and updating of NRDC's membership database, which is a listing of those persons who are members of NRDC.

3. NRDC is a membership organization incorporated under the laws of New York. It is recognized as a not-for-profit corporation under section 501(c)(3) of the United States Internal Revenue Code.

4. NRDC currently has hundreds of thousands of members nationwide, including members in California and Florida.

5. NRDC has offices throughout the country, including in San Francisco and Santa Monica, California, and in Bozeman, Montana.

6. When someone becomes a member of NRDC, they authorize NRDC to take legal action on their behalf to protect the environment and public health.

7. NRDC's mission statement declares that "The Natural Resources Defense Council's purpose is to safeguard the Earth: its people, its plants and animals, and the natural systems on which all life depends." NRDC's mission includes maintaining the effectiveness of antibiotics used

in human medicine and the protection of threatened and endangered species from further population decline and extension.

8. I understand that the U.S. Environmental Protection Agency authorized streptomycin to be used as a pesticide on citrus crops. NRDC submitted comments objecting to this registration. After EPA finalized the registration, NRDC filed this case. NRDC's lawsuit fits squarely within the organization's mission and its longstanding efforts to protect antibiotics and threatened and endangered species.

9. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

DATED: July 12, 2022

Katonah, NY

Respectfully submitted,

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF STEFFANIE STRATHDEE

I, Steffanie Strathdee, do hereby affirm and state:

1. I am a member of the U.S. Public Interest Research Group (U.S. PIRG).

2. I am an infectious disease epidemiologist with a PhD from the University of Toronto. Currently, I am the Associate Dean of Global Health Sciences and Harold Simon Distinguished Professor in the Department of Medicine at the University of California San Diego School of Medicine. I also founded and am the co-director of the center for Innovative Phage

Applications and Therapeutics at the University of San Diego School of Medicine.

3. I am concerned about the rise of antibiotic resistant superbugs, not only in the United States but globally. Time Magazine named me one of the "Health Care 50" in 2018 for my work addressing these superbugs.

4. My concern about antibiotic resistant superbugs comes from my family's own experience. In 2015, my husband acquired a deadly ESKAPE[1] pathogen while we were travelling in Egypt. At first, we thought it was food poisoning, but a gallstone caused an abscess where the superbug went. My husband was medevaced to Germany and then to the United States and back to UC San Diego, where we both work.

5. Seeing my colleagues care for my husband and thinking he was going to die was the most difficult thing I've gone through in my entire life.

6. While infected with the superbug, my husband spent nine months in the hospital, four months in the ICU, and two months on a

[1] The acronym ESKAPE is used for the scientific names of a group of six multidrug resistant pathogens.

ventilator. He had seven incidents of septic shock during this time. During this time the pathogen acquired more resistance to antibiotics.

7. The heavy use of antibiotics also killed the friendly bacteria and made more space for the superbug to move in. The antibiotics of last resort used were hard on his organs, and he had lingering kidney issues as a result.

8. My husband's condition only improved when we turned to phage therapy, which uses viruses to fight and kill often antibiotic resistant bacteria, as his primary treatment regimen.

9. My husband continues to suffer from the effects of this infection. He is at a higher risk for complications for COVID. If he contracted COVID, he would be prone to suffer from secondary bacterial infections that increase his risks. He also has some congestive heart failure, is insulin dependent, and has only one third of his pancreas left. In the last three years, he has had three episodes of septic shock because of a lingering gut issue. These cases of septic shock occurred due to constrictions in his

intestine that were a result of his superbug infection, and each time these incidents of sepsis led him to be taken to the emergency department.

10. The need to care for my husband has also affected me and my step-daughters. I took a year-and-a-half sabbatical to care for my husband. The experience took a heavy psychological toll, and my family and I continue to have post-traumatic stress disorder from it. My family experiences a post-ICU syndrome, a form of post-traumatic stress disorder, from it, which will never really go away. Just talking about my husband's infection takes me right back to it. We have seen a psychologist and undergone eye-movement desensitization and reprocessing therapy for this.

11. My husband and I coauthored a book, *The Perfect Predator*, about his superbug infection and its treatment. A lot of work with that book has been about raising awareness of superbugs and showing people how they can stop the spread. Through this work, I have come into direct contact with many other people whose family members have had

experiences just like my own. These superbugs used to be treatable, but no longer are because of the overuse of antibiotics, especially in agriculture.

12. Since then, I have done more research and work in the field of antimicrobial resistance. I serve on a World Health Organization taskforce on antimicrobial resistance in Southeast Asia. I know there is a need to research not just new treatments to antibiotic resistant bacteria but also to stop misuses and overuse in agriculture.

13. In 2020, I co-authored a paper published in *The Lancet*, a top medical journal, about how COVID is exacerbating the antimicrobial resistance crisis. People infected with COVID may survive that disease but die from a superbug. The fear of secondary infections in COVID patients is also leading to over-prescription of antibiotics.

14. Because of my husband's risk for secondary bacterial infections from COVID, my family and I have taken extra precautions during the pandemic. We continue to stay largely housebound and limited to outdoor activities to minimize risk of COVID and secondary infections because of

our concern that antibiotics used in treatment could be ineffective or could further weaken my husband.

15. I know through my research that unsuccessful treatment of bacterial infections due to antimicrobial resistance result in over 1.2 million annual deaths worldwide.

16. I know that streptomycin is a medically important antibiotic. It is important not to overuse it because it will promote more resistance.

17. In 2019, my husband testified about his experiences with an antibiotic resistant superbug infection before the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). I know that PACCARB created a National Action Plan that calls for reductions in the use of medically important antibiotics, such as streptomycin, in agriculture.

18. I am aware of alternatives to the use of antibiotics in agriculture, and I do not believe we should resort to the use of antibiotics for crops when there is such a clear risk.

19. I live in Carlsbad, California, and am aware that there are nearby commercial citrus groves in this part of the state. I also have citrus in my yard.

20. My family is active outdoors as a way to help my husband get his strength back. We hike mostly around our neighborhood, but also in other areas further away in California that may be near commercial citrus. We are also planning on a trip this coming month near Santa Barbara, which I understand is near commercial citrus groves.

21. I worry that the increased use of streptomycin and other antibiotics in agriculture will contribute to the rise of superbugs, such as the one that infected my husband.

22. I believe that revoking the Environmental Protection Agency's approval of streptomycin would prevent the use of streptomycin on citrus. Medically important antibiotics like streptomycin should never be used in agriculture, and such a use directly contradicts the World Health Organization, United Nations, and PACCARB National Action Plan's recommendations. The overuse of antibiotics in agriculture contributes to

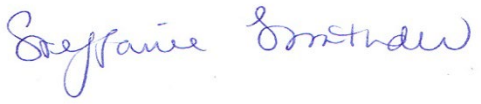
the rise of resistant superbugs like the one that infected my husband. I therefore support U.S. PIRG's petition challenging the federal government's approval of streptomycin under the Federal Insecticide, Fungicide, and Rodenticide Act.

23. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

DATED: June _24_, 2022

Carlsbad, California

Respectfully submitted,



_____

Steffanie Strathdee, PhD

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

DECLARATION OF ANDRE DELATTRE

I, Andre Delattre, declare as follows:

1. I am the chief operating officer for programs and senior vice president for The Public Interest Network. I oversee all aspects of programs, including program implementation and administration for the United States Public Interest Research Group, Inc. ("U.S. PIRG"). I have been in this role since 2017.

2. U.S. PIRG is a membership organization incorporated under the laws of Washington, D.C. It is recognized as a tax-exempt social welfare organization under section 501(c)(4) of the U.S. Internal Revenue Code.

3. I am familiar with the membership rolls of U.S. PIRG, which has tens of thousands of members nationwide.

4. U.S. PIRG's mission is to stand up to powerful special interests on behalf of the American public, and it works to win concrete results for the public's health and well-being. U.S. PIRG is an advocate for the public interest, and it speaks out for a healthier, safer world in which every individual is freer to pursue his or her own individual well-being and the common good. With a network of researchers, advocates, organizers, and students across the country, U.S. PIRG takes on special interests on issues such as public health and consumer protection, among others. U.S. PIRG's mission includes maintaining the effectiveness of antibiotics used in human medicine.

5. I understand that the U.S. Environmental Protection Agency authorized streptomycin to be used as a pesticide on citrus crops. U.S.

PIRG submitted comments objecting to this registration. After EPA finalized the registration, U.S. PIRG joined with other groups to file this case. U.S. PIRG's lawsuit fits squarely within the organization's mission and its longstanding efforts to protect antibiotics.

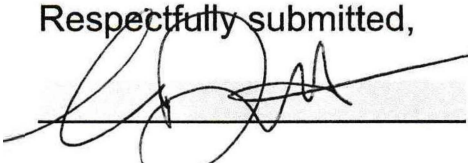
6. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

DATED:

July 14, 2022

CHICAGO, IL

Respectfully submitted,



Andre Delattre