No. 21-70719

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK, et al.,
Petitioners,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

On Petition for Review of Final Agency Action of the
United States Environmental Protection Agency

CORRECTED BRIEF FOR RESPONDENTS

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GLOSSARY

ARRT	Antibiotic Resistance Review Team, U.S. EPA
BEAD	Biological and Economic Analysis Division, U.S. EPA
EFED	Environmental Fate and Effects Division, U.S. EPA
EPA	United States Environmental Protection Agency
ESA	Endangered Species Act
FIFRA	Federal Insecticide Fungicide and Rodenticide
FDA	Food and Drug Administration
PPE	personal protective equipment
Services	U.S. Fish and Wildlife Service, National Marine Fisheries Service, or both

INTRODUCTION

Petitioners challenge EPA's 2021 decision to amend registrations for two existing pesticide products containing the active ingredient streptomycin sulfate.[1] These registration amendments allow a new, time-limited use on citrus crops that will aid in managing the effects of two debilitating bacterial diseases: citrus greening and citrus canker. Between 2012 and 2016, citrus greening alone caused $4.4 billion in economic losses.

Petitioners allege that EPA violated the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA") by failing to ensure that this new use of streptomycin would not cause unreasonable adverse effects on the environment, and that EPA violated the Endangered Species Act ("ESA") by failing to consult with the U.S. Fish and Wildlife Service, National Marine Fisheries Service, or both (collectively, the "Services") before EPA approved the registration amendments at issue.

The administrative record supports EPA's FIFRA evaluation of the risks and the benefits of streptomycin's new use. EPA conducted risk

[1] Although the active ingredient in the amended registrations at issue here is streptomycin sulfate, EPA and Petitioners generally refer to it as "streptomycin".

assessments to analyze streptomycin's potential adverse effects, including the potential development of antibiotic resistance in human pathogens. Although EPA concluded that the new use of streptomycin presents limited risks, EPA nevertheless required monitoring reports and mitigation measures that address potential antibiotic resistance in human pathogens, worker exposure, and spray drift. Outweighing the risks, the approved new use provides an important tool to ameliorate citrus greening and citrus canker. The Court should therefore reject Petitioners' FIFRA challenges.

However, EPA acknowledges that it did not determine whether its action may affect listed species or critical habitat before approving these registration amendments. EPA therefore respectfully requests that this Court remand the challenged registration approvals without vacatur, to allow EPA to make those determinations and take any additional actions if appropriate.

Vacatur of the registration amendments is not warranted. EPA considered the new uses' potential adverse effects under FIFRA and concluded that the risks would be limited, so there is no basis in the record of this case to conclude that there will be significant harm from

leaving the amended registrations in place. Conversely, vacatur would deprive growers of this tool for managing these two devastating citrus diseases.

STATEMENT OF JURISDICTION

This court has jurisdiction over the petition for review pursuant to 7 U.S.C. § 136n(b), which provides for judicial review in the courts of appeals "of any [FIFRA] order issued by the Administrator following a public hearing." EPA finalized the challenged orders in two registration amendments issued under 7 U.S.C. § 136a(c)(5). *See* EPA-HQ-OPP-2016-0067-0232 (1-ER-3–28); EPA-HQ-OPP-2016-0067-0233 (1-ER-29–32). EPA issued the registration amendments after notice-and-comment proceedings. *See* Final Registration Decision for the New Use of the Active Ingredient Streptomycin Sulfate on Citrus Crop Group 10-10 (Jan. 12, 2021) ("Final Decision Notice") at 15-16 (1-ER-47–48).[2] Pursuant to 40 C.F.R. § 23.6, the orders became final for the purpose of this Court's jurisdiction on January 26, 2021. This petition for review was timely filed

[2] A registration decision issued after notice-and-comment constitutes an order "following a public hearing." *Nat'l Fam. Farm Coal. v. EPA*, 960 F.3d 1120, 1132 (9th Cir. 2020).

on March 25, 2021, "within 60 days after the entry of [the] order." 7 U.S.C. § 136n(b).

STATEMENT OF THE ISSUES

(1) Does substantial evidence in the administrative record support EPA's conclusion that the new uses of streptomycin would not cause unreasonable adverse effect on the environment?

(2) Is vacatur of the registration amendments an appropriate remedy in light of the disruption that cancellation would cause?

STATEMENT REGARDING ADDENDUM TO BRIEF

Except for the following, which are appended to this brief, all applicable statutes, etc., are contained in the addendum to Petitioners' Brief:

5 U.S.C. § 701;

7 U.S.C. §§ 136j, 136p;

Section 10013 of the Agricultural Act of 2014;

Section 10115 of the 2018 Farm Bill;

40 C.F.R. §§ 155.56, 155.57, 158.1, 158.30, 158.400, 180.41(c)(15); and

50 C.F.R. §§ 402.02, 402.13, 402.40, and 402.46.

STATEMENT OF THE CASE

I. Framework For Pesticide Registrations

A. Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA generally precludes the distribution or sale of any pesticide unless it is "registered" by EPA. 7 U.S.C. § 136a(a). The registration process begins with submission of a "statement," which includes, among other things, the name and complete "formula of the pesticide." *Id.* § 136a(c)(1). EPA then provides "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" and allows opportunity for comments. *Id.* § 136a(c)(4).

EPA issues a license, known as a "registration," that allows each specific pesticide product to be legally sold or distributed. *Id.* §§ 136a(a), 136j(a)(1)(A)–(C); *see also Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 912 (9th Cir. 2020). "The terms and conditions on the license include exactly what product can be sold, the specific packaging it must be sold in, and labeling that contains instructions on proper use." *Nat'l Fam. Farm*, 966 F.3d at 912 (citing 7 U.S.C. § 136(p)). It is unlawful to use a pesticide "in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G).

EPA "shall register a pesticide" if it determines that:

> (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 [FIFRA];
>
> (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.

Id. § 136a(c)(5). A pesticide product's labeling is integral to EPA's registration decision and is the primary means of accomplishing FIFRA's mandate to prevent unreasonable adverse effects.

To determine whether an application for a registration amendment adding a new use to an existing registration should be granted, EPA evaluates whether the new use is likely to cause unreasonable adverse effects. 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." *Id.* § 136(bb). Put another way, under FIFRA, Congress expressly directs EPA to balance the risks and benefits of granting the registration amendment.

EPA must also periodically review pesticide registrations. *Id.* § 136a(g); 40 C.F.R. § 155.40 *et seq*. A registration review reflects EPA's "determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA." 40 C.F.R. § 155.57. EPA may also make an interim registration review decision to, among other things, "identify data or information required to complete the review." *Id.* § 155.56.

Streptomycin is currently undergoing registration review, under the docket number EPA-HQ-OPP-2008-0687. EPA signed a proposed interim decision in December of 2018, in which EPA indicated that it was assessing whether it needed additional data to assess the effects of streptomycin on pollinators, among other things. *See* EPA, Streptomycin Proposed Interim Registration Review Decision (2018), EPA-HQ-OPP-2008-0687-0024, at 15-16 (SER-119–120).

FIFRA's regulations set out the kinds of data and information that EPA requires from applicants before making regulatory judgments about whether to grant a registration or a registration amendment. *See generally* 40 C.F.R. Part 158; 40 C.F.R. § 158.1(a). EPA "unconditionally" approves registration applications where EPA determines that "no additional data are necessary to make the determinations required by [7

U.S.C. § 136a(c)(5)]," *id.* § 152.112(c), and finds that the pesticide will not generally cause unreasonable adverse effects on the environment. If, on a product-by-product basis, EPA determines that the data that the regulations require from the applicant "is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment," then EPA may decide that it needs to impose additional data requirements. *Id.* § 158.75. However, these regulations do not restrict how EPA "uses or evaluates the data and information in its risk assessment and risk management decisions, or the regulatory determinations that may be based upon the data." *Id.* § 158.1(b)(3). Instead, EPA has "the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review." *Id.* § 158.30(a).

For insect pollinators in particular, EPA's FIFRA regulations require a honeybee acute contact toxicity study and conditionally require two additional studies based on the results of the acute contact toxicity study. *Id.* § 158.630(d) (table). EPA has also developed various guidance

documents that together form a bee-specific risk assessment framework. *See* EPA, Process for Requiring Exposure and Effects Testing for Assessing Risks to Bees During Registration and Registration Review (2016) ("Pollinator Process Guidance") (SER-140–165). *See generally Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 524-26 (9th Cir. 2015). These guidance documents reflect EPA's most up-to-date efforts to ascertain what data may be needed in order to assess the effects of pesticides on bee populations, and are more current than the data requirement regulation, 40 C.F.R. § 158.630(d). In some situations, EPA's guidance prompts EPA to require additional types of studies beyond those required by regulation. EPA has not yet revised its regulatory data requirements, but it has published a flowchart clarifying when in the registration process EPA might require additional pollinator data to support a registration. *See* Pollinator Process Guidance at 9, 15-16 (SER-148, 154-155). For a new outdoor use of an existing active ingredient with existing outdoor uses, such as the registration amendments at issue here, if the "application for an additional outdoor use is submitted before the issuance of the final rule amending 40 CFR Part 158," the guidance provides that EPA will conduct its review "with existing data and

consider benefits, extent of use, and mitigation where appropriate to make safety finding." *Id.* at 15-16 (SER-154–155). Any additional data that EPA determines is needed "will be called in under registration review criteria … ." *Id.* at 16 (SER-155).

B. Endangered Species Act

ESA Section 7(a)(2) directs each federal agency to insure that "any action authorized, funded, or carried out by such agency … is not likely to jeopardize the continued existence of" a listed species or destroy or adversely modify designated critical habitat for such a species. 16 U.S.C. § 1536(a)(2). To facilitate compliance with those mandates, the ESA's implementing regulations outline a process whereby federal "action agencies" (here, EPA) consult with the appropriate expert "consulting agency" (either the National Marine Fisheries Service or the U.S. Fish & Wildlife Service or both, depending on the species involved) to, among other things, analyze the potential impacts of a proposed action on listed species and designated critical habitat. 50 C.F.R. §§ 402.13(a), 402.14(b)(1); *see also id.* § 402.40(b).

Consultation is required whenever a proposed federal action "may affect" listed species or critical habitat. 50 C.F.R. § 402.14(a). Agency

"action" and "effects of the action" are defined terms under the ESA. *Id.* § 402.02. If the action will not affect listed species or designated critical habitat, then consultation is not required. *Sw. Ctr. for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1447-48 (9th Cir. 1996); *Nat'l Fam. Farm*, 966 F.3d at 924.

If, however, the action agency determines that the action "may affect" listed species or critical habitat, it must consult, either formally or informally. 50 C.F.R. §§ 402.13-402.14, 402.46. Formal consultation is required unless the action agency determines, with the consulting agency's written concurrence, that the proposed action is "not likely to adversely affect" a listed species or critical habitat. *Id.* §§ 402.13(c), 402.14(b)(1). If formal consultation is required, then the consulting agency must prepare a biological opinion stating whether the proposed action is likely to "jeopardize the continued existence of" any listed species or destroy or adversely modify critical habitat. 16 U.S.C. § 1536(b)(3); 50 C.F.R. §§ 402.14, 402.46.

II. Factual Background[3]

A. Historical use of streptomycin as an active ingredient in pesticides

Streptomycin is a broad-spectrum aminoglycoside antibiotic and fungicide derived from *Streptomyces griseus*, a bacterium commonly found in soil. *See* Final Decision Notice at 2 (1-ER-34); *see also* Review of AgroSource's Analysis of Streptomycin's Safety with Regard to Its Microbiological Effect on Bacteria of Human Health Concern (FDA/CVM Guidance to Industry #152) for a Section 3 Registration on Citrus Crop Group 10-10 (Oct. 25, 2017) ("Safety Review") at 4 (3-ER-287). Although it is used to treat bacterial infections in humans and in animals, streptomycin has also been used commercially to control bacterial plant diseases since the 1950s. Final Decision Notice at 2, 10 (1-ER-34, 42); *see also* Response to Comments Received to the Streptomycin Proposed New Uses on Citrus Group 10-10 Docket (Jan. 11, 2021) ("EPA Response to

[3] This Factual Background relies in part on non-record sources because, as explained in the Standard of Review section below, the remedial question of whether to grant EPA's request to remand without vacating the amended registrations is an equitable one that may take account of facts outside the record. However, the Court's review of Petitioners' FIFRA claims is limited to the administrative record, and Respondent's citations in Argument I are accordingly to only the administrative record.

Comments") at 23 (2-ER-162). Streptomycin sulfate is an active ingredient in pesticide products long registered for use on various crops, including apples, pears, celery, pepper, potatoes, tobacco, and tomatoes. Final Decision Notice at 2 (1-ER-34); *see also* Review of Benefits of a New Use of Streptomycin Sulfate (FireWall 50WP) on Citrus Crop Group 10-10 (Nov. 22, 2017) ("Benefits Memo") at 3 (3-ER-295). It is also registered for use on ornamental house plants, such as chrysanthemum, dieffenbachia, philodendron, and roses, and in home gardens. *See, e.g.*, Final Decision Notice at 6 (1-ER-38).

More recently, the citrus industry has faced serious challenges from huanglongbing (citrus greening), which is a currently uncurable—and typically fatal—plant disease spread by the invasive Asian citrus psyllid that severely impacts the fruit yield of infected trees and the American citrus industry. *See* Benefits Memo at 1-2, 4 (3-ER-293–294, 296). Starting in 2016, EPA authorized emergency exemptions under FIFRA Section 18, 7 U.S.C. § 136p, that allowed streptomycin's use on citrus crops in Florida and California to manage the effects of citrus greening. Final Decision Notice at 2 (1-ER-34); *see also* Benefits Memo at 3 (3-ER-295). These emergency exemptions authorized the use of certain

streptomycin products as a foliar treatment—that is, applying the pesticide directly to leaves. Benefits Memo at 3 (3-ER-295).

These diseases have profound effects on infected citrus trees, such as premature leaf and fruit drop, changes to the size and shape of fruit, and tree decline leading to death. Benefits Memo at 1-3 (3-ER-293–295); *see also* Streptomycin Sulfate – BEAD Response to Public Comments Received on the Proposed New Use for Citrus Crop Group 10-10 and on the Preliminary Interim Registration Review Decision (Jan. 11, 2021) ("BEAD Response to Comments") at 7 (2-ER-171). Since first detected in Florida in 2005, citrus greening in particular has devastated the American citrus industry, causing the loss of about 100,000 acres of citrus, billions of dollars of lost revenue, and thousands of jobs. Declaration of Kimberly Nesci in Support of EPA's Motion for Remand Without Vacatur, Feb.1, 2022 ("Nesci Decl.") ¶ 8 (SER-006); *see also* Final Decision Notice at 14-15 (1-ER-46–47); *see also* BEAD Response to Comments at 7 (2-ER-175). Indeed, citrus greening has been called "the most destructive disease of citrus known." Gottwald, T.R. et al., *Inconsequential effect of nutritional treatments on huanglongbing control,*

fruit quality, bacterial titer and disease progress, Crop Protection, Vol. 36 (June 2012) at 73 (SER-166).

B. 2021 registration amendments at issue here

In November of 2015, Geo Logic Corporation and AgroSource, Inc. sought to amend the registrations of two existing products to allow the use of streptomycin on crop group 10-10, which includes citrus crops such as grapefruits, limes, and oranges. Final Decision Notice at 2 (1-ER-34); *see also* 40 C.F.R. § 180.41(c)(15) (identifying Crop Group 10-10).[4] EPA published receipt of the applications in the *Federal Register* and received no comments. Final Decision Notice at 15-16 (1-ER-47–48). EPA then prepared a review of the benefits of the new uses, *see* Benefits Memo (3-ER-293–304), an environmental and ecological effects assessment, *see* Section 3 Proposed New Use of Streptomycin Sulfate on Citrus, Crop Group 10-10 (Nov. 20, 2017) ("Environmental Fate and Effects Division Assessment") (3-ER-368–376), and an assessment of streptomycin's potential to select for resistance in microbes of human health concern,

[4] EPA added crop group 10-10 in 2010, as part of a rulemaking to allow more flexibility in setting pesticide tolerances under the Federal Food, Drug, and Cosmetic Act. *See* 75 Fed. Reg. 76284, 76285 (Dec. 8, 2010) (SER-177).

Safety Review (3-ER-284–292). EPA published its intent to grant the registration amendments, after which it received more than 40,000 comments, which EPA summarized and responded to. *See* Final Decision Notice at 16 (1-ER-48), EPA Response to Comments (2-ER-140–168), BEAD Response to Comments (2-ER-169–180); Streptomycin Sulfate – ARRT Response to Public Comments Received on the Proposed New Use for Citrus Crop Group 10-10 (Jan. 11, 2021) ("ARRT Response to Comments") (2-ER-181–191); Streptomycin Sulfate – EFED Response to Public Comments Received on the Proposed New Use for Citrus Crop Group 10-10 and the Registration Review Proposed Interim Decision (Jan. 11, 2021) ("EFED Response to Comments") (2-ER-192–202).

On January 11, 2021, EPA granted unconditional registration amendments for one technical use product, EAC Streptomycin Manufacturing Use Product (EPA Reg. #71185-4) (1-ER-29–32), and one end-use product, Agri-Seed 50WP (EPA Reg. #80990-3) (1-ER-3–28), making streptomycin one of just two antibiotics registered for managing citrus greening and citrus canker diseases.

III. Procedural Background

On February 4, 2022, EPA filed a motion asking the Court to remand without vacatur EPA's decision to amend the registrations. EPA Mot. for Remand, ECF No. 42-1. Petitioners filed a cross-motion 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. On April 22, 2022, the Court denied both motions "without prejudice to the parties renewing the arguments in their respective briefs on the merits." Order, ECF No. 51.

SUMMARY OF THE ARGUMENT

Substantial evidence in the administrative record supports EPA's conclusion under FIFRA that the new uses of streptomycin would not cause unreasonable adverse effects on the environment. Contrary to Petitioners' arguments, EPA addressed 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, and EPA required the label for the amended registrations to include numerous measures to mitigate that risk. Those measures include limits on spray direction and on reentry into treated fields, requirements for personal protective equipment, and a monitoring program that will allow EPA to reassess ecological and human health risks, including the

potential development of antibiotic resistance in human and in plant pathogens, based on actual usage data. EPA also addressed risks to bees, finding that streptomycin is practically nontoxic to them. The data on which EPA relied was fully consistent with FIFRA's regulations and with EPA's guidance on data requirements for pesticides that could affect pollinators. Against these limited risks, EPA determined that streptomycin aids in managing the symptoms of citrus greening disease and provides a valuable alternative to other methods of managing citrus canker.

However, EPA acknowledges that it did not make ESA effects determinations for the amendments, and that it must take further action to comply with the ESA on remand. But EPA's error does not rise to the level that justifies vacatur when weighed against vacatur's disruptive consequences. EPA expressly considered the pesticide's effect on the environment in issuing the amended registrations and found limited risk of environmental harm. In contrast, vacatur would harm growers by depriving them of a valuable tool for managing the effects of two devastating citrus diseases. Even if the Court were to find EPA's analysis to be insufficient under FIFRA, that analysis meets the standard for

remand without vacatur. And, on remand, EPA could reaffirm its decision to grant the amended registrations for this use. The equities therefore weigh in favor of leaving the registration amendments in place during the remand period, and EPA satisfies the standard for voluntary remand without vacatur.

STANDARD OF REVIEW

Under FIFRA, EPA's orders granting the unconditional 2021 registration amendments "shall be sustained if [they are] supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). This standard is "extremely deferential," *Singh-Kaur v. INS,* 183 F.3d 1147, 1149 (9th Cir. 1999) (citations omitted), more so than the "clearly erroneous" standard for appellate review of trial court findings. *Dickinson v. Zurko*, 527 U.S. 150, 162, 164 (1999). Courts "must affirm the Administrator's finding where there is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion even if it is possible to draw two inconsistent conclusions from the evidence." *NRDC v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013) (internal quotation marks and citations omitted).

A reviewing court "should not supplant the agency's findings merely by identifying alternative findings that could be supported by substantial evidence." *Arkansas v. Oklahoma*, 503 U.S. 91, 113 (1992); *see also The Lands Council v. McNair*, 537 F.3d 981, 988 (9th Cir. 2008) (courts should not "act as a panel of scientists" that "instructs [a federal agency] how to validate its hypotheses," "chooses among scientific studies," or "orders the agency to explain every possible scientific uncertainty"), *overruled in part on other grounds by Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7 (2008). Agency decisions must be sustained so long as the agency's path "may reasonably be discerned." *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974).

When, as here, "the agency is making predictions, within its area of special expertise, at the frontiers of science" a reviewing court must "generally be at its most deferential." *NRDC*, 735 F.3d at 877 (quotation marks omitted); *see also Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983). An agency "is not required to support its finding with anything approaching scientific certainty." *ASARCO, Inc. v. Occupational Safety & Health Admin.*, 746 F.2d 483, 490 (9th Cir. 1984) (quotation marks omitted).

For Petitioners' ESA claim, the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq*., provides the standard of review because the statute itself does not specify a standard. Under the APA, a reviewing court may only set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *see also NRDC v. EPA,* 38 F.4th 34, 44 (9th Cir. 2022). A decision is arbitrary and capricious only if the agency "relied on factors Congress did not intend it to consider, entirely failed to consider an important aspect of the problem, or offered an explanation that runs counter to the evidence before the agency or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *The Lands Council v. McNair*, 629 F.3d 1070, 1074 (9th Cir. 2010) (internal quotation marks and citation omitted).

This Court has recognized that the distinction between the "substantial evidence" and "arbitrary and capricious" tests is largely semantic, particularly as applied to review of agency factual conclusions. *See Bonnichsen v. United States*, 367 F.3d 864, 880 n.19 (9th Cir. 2004); *see also Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed.eral Rsrv. Sys.*, 745 F.2d 677, 683-84 (D.C. Cir. 1984) (Scalia, J.)

(noting that this appeared to be the consensus view). *But see Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 533 (9th Cir. 2015) (N.R. Smith, J., concurring).

Voluntary remand of a challenged agency action is proper where the agency seeks to reconsider its initial action. *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012); *see also NRDC*, 38 F.4th at 60 ("Courts generally grant an agency's request for voluntary remand unless the request is frivolous or made in bad faith."). To determine whether to vacate, the court weighs the seriousness of the error against "the disruptive consequences of an interim change that may itself be changed," the extent to which "either vacating or leaving the decision in place would risk environmental harm," and whether the agency would likely "adopt the same rule on remand." *NRDC*, 38 F.4th at 51-52 (citations omitted).

ARGUMENT

I. Substantial Evidence In The Administrative Record Supports EPA's Decision To Approve The Registration Amendments Under FIFRA.

EPA determined that the new use of streptomycin will not cause unreasonable adverse effects on the environment. Petitioners argue that EPA inadequately addressed the potential that human health pathogens

could develop increased antibiotic resistance, that EPA inadequately addressed risks to pollinators, and that EPA overstated the benefits of streptomycin. These arguments fail because EPA's conclusion regarding unreasonable adverse effects is supported by substantial evidence in the administrative record.

A. The amended registrations meet FIFRA's requirements.

Before granting the registration amendments at issue, EPA thoroughly evaluated both ecological and human health risks, including the potential development of antibiotic resistance in human and in plant pathogens, and weighed those limited risks against the benefits of this additional use of streptomycin. EPA concluded that, in light of the available evidence and the required mitigation measures, granting the registration amendments would not cause unreasonable adverse effects on the environment.

1. Streptomycin is practically non-toxic and poses limited risk.

As FIFRA requires, EPA considered the ecological and the human health risks of granting the registration amendments adding a new use of streptomycin on citrus crop group 10-10.

EPA conducted an environmental risk assessment and found that the risks for the new uses of streptomycin were much like those of other, already registered uses. Final Decision Notice at 3 (1-ER-35). EPA analyzed streptomycin's environmental effects using exposure and toxicity data, particularly for mammals, birds, fish, invertebrates, and plants. *Id.* at 4-5 (1-ER-36–37); *see also* Environmental Fate and Effects Division Assessment (3-ER-368–376). After reviewing a variety of data, *see, e.g.*, Final Decision Notice at 2-3 (1-ER-34–35); Environmental Fate and Effects Division Assessment at 4-9 (3-ER-371–376), EPA concluded that the environmental effects of the new uses of streptomycin would be minimal, and that the data suggests streptomycin is "practically nontoxic" to birds, mammals, fish, and aquatic invertebrates on an acute exposure basis. Environmental Fate and Effects Division Assessment at 4, 7 (3-ER-371, 374). At the exposure levels contemplated by the new uses (which are lower than the exposure levels contemplated in streptomycin's registered uses on apples and pears), EPA found that the only risks of concern to non-target organisms were for mammals (on a chronic basis) and sensitive aquatic nonvascular plants. Final Decision Notice at 4-5,

17 (1-ER-36–37, 49), Environmental Fate and Effects Division Assessment at 8-9 (3-ER-375–376).

As for pollinators, streptomycin is also classified as "practically nontoxic" to honey bees, Final Decision Notice at 4 (1-ER-36), Environmental Fate and Effects Division Assessment at 4 (3-ER-371), and the record includes the required honeybee acute contact toxicity study pursuant to 40 C.F.R. § 158.630(d). *See* Certified Index to the Administrative Record, ECF No. 28-2, at 17 (line 344), 19 (line 399). EPA's ecological risk assessors recognized that additional data could allow EPA to more fully assess the products' effects on pollinators. Environmental Fate and Effects Division Assessment at 2, 4 (3-ER-369, 371); EFED Response to Comments at 3-4, 5-6, 9 (2-ER-194–195, 196–197, 200). However, consistent with its guidance, EPA explained that it would consider whether to require any additional bee data in the context of EPA's ongoing registration review for all streptomycin products. Final Decision Notice at 4 (1-ER-36); *see also* Pollinator Process Guidance at 15-16 (SER-154–155) (flowchart).

EPA also conducted risk assessments to evaluate the risk to human health, concluding there are "no risks of concern." Final Decision Notice

at 4-5 (1-ER-36–37). EPA explained that available studies and "conclusions that can be drawn from the decades of use of streptomycin as a human antibiotic drug without significant incidents" were enough to assess the compound's risks. *Id.* EPA found no evidence that streptomycin was a carcinogen, *id.*, no indication of neurotoxicity, *id.* at 6 (1-ER-38), no residual exposure concerns, *id.*, and no indication of a dermal hazard, *id.* at 6-7 (1-ER-38–39). EPA also assessed the risks of the additional uses on citrus to human health, concluding (after reviewing a "database of studies") that "[t]here are no risks of concern." *Id.* at 5 (1-ER-37).

Next, EPA evaluated the risk that this use of streptomycin would increase antibiotic resistance developing in human pathogens. Final Decision Notice at 7-13 (1-ER-39–45), Safety Review (3-ER-284–292). EPA examined three areas where exposed bacteria might develop resistance: the environment (namely in treated orchards); the general public, through consuming food with streptomycin residues; and agricultural workers, through their daily activities. Final Decision Notice at 10 (1-ER-42). EPA concluded that it "is unlikely" that any current resistance to streptomycin in "clinical" applications, i.e., human

pharmaceuticals, "is due to streptomycin's use in agriculture." *Id.* at 12 (1-ER-44). Thus, EPA found an overall "medium" risk that granting the amended registrations could cause increased antibiotic resistance in human pathogens. *Id.*

In addition to resistance in human pathogens, EPA also considered whether antibiotic resistance may develop in plant pathogens, *Id.* at 13-14 (1-ER-45–46). Although the likelihood of such resistance is unknown, *id.* at 13 (1-ER-45), EPA determined that certain management strategies could slow the development of resistance in plant pathogens and prolong the useful life of streptomycin on agricultural products. *Id.* at 14 (1-ER-46).

EPA also acted to reduce identified risks. Recognizing "uncertainties" in its risk assessment, Safety Review at 8 (3-ER-291), EPA imposed a program to monitor antibiotic resistance and a 7-year expiration on these amended registrations to allow EPA to revisit the risk picture as more data becomes available based on actual usage. Final Decision Notice at 16-17 (1-ER-48–49). And, as part of EPA's approval, the label:

- requires applicators to reduce spray drift that might impinge on neighboring fields and communities, such as "direct spray into the canopy[] and turn off outward pointing nozzles at row ends and when spraying outer rows."
- limits circumstances where human pathogens might make up more than a relatively minor component of the general agricultural environment, by prohibiting application "in orchards [where] the soil has been fertilized with animal waste/manure or human biosolids."
- prohibits reentry into treated areas for 12 hours.
- requires applicators to wear personal protective equipment including "coveralls over short-sleeved shirt and short pants" and approved respirators.
- directs users to make only full-strength applications, in order to avoid sub-lethal exposure to the target.
- and directs users to rotate between use of streptomycin and other different methods of control.

Final Decision Notice at 18-20 (1-ER-50–52). EPA developed all of these mitigation measures in cooperation with its federal partners in the FDA, Centers for Disease Control, and Department of Agriculture, in recognition of the grave concerns that antibiotic resistance in human pathogens presents. *Id.* at 18 (1-ER-50).

2. Streptomycin provides important benefits for citrus growers, especially in Florida.

EPA also evaluated the potential benefits provided by the new use of streptomycin. *Id.* at 14-15 (1-ER-46–47); Benefits Memo (3-ER-293–304). EPA acknowledged that streptomycin will not eliminate either citrus greening or citrus canker, but EPA found that the new use could improve tree health and vigor and increase the quantity and quality of the fruit, thereby potentially providing a tool to ameliorate those diseases' effects. Benefits Memo at 4-6 (3-ER-296–298) (benefits regarding citrus greening include improved tree health and higher fruit yields and quality), *id.* at 7-9 (benefits regarding citrus canker include increased yields, reduced fruit drop and reduced fruit cankers) (3-ER-299–301); *see also* BEAD Response to Comments at 7 (2-ER-175). Streptomycin also provides an alternative to copper-based treatments for citrus canker. Benefits Memo at 6-7 (3-ER-298–299). Although copper is

effective against citrus canker, copper is phytotoxic and can cause "fruit blemishes and reduced fruit quality that lower[] the value of grapefruits for fresh market." *Id.* at 7 (3-ER-299). Streptomycin thus not only reduces the amount of copper that is introduced into the environment, its use also lowers the chances that copper-resistant strains of the pathogen that cause citrus canker will develop. *Id.*

The new use of streptomycin on citrus is also an effective tool to manage pest resistance. *See, e.g.*, Final Decision Notice at 13 (1-ER-45) ("general considerations for prudent agricultural use" include avoiding practices that rely on one chemical to control disease), Benefits Memo at 5 (3-ER-297). EPA registered another antibiotic, oxytetracycline, for use on citrus in 2018. Final Decision Notice at 15 (1-ER-47), BEAD Response to Comments at 8 (2-ER-176). Because streptomycin and oxytetracycline have different modes of action, the registrations at issue can serve an important role in resistance management strategies. Benefits Memo at 5 (3-ER-297). Streptomycin use on citrus therefore helps reduce the likelihood that plant pathogens will develop resistance to an individual pesticide.

B. Petitioners' contrary arguments are insufficient to overturn EPA's decision.

Petitioners' make three main arguments. They argue that EPA failed to adequately assess 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, or the risk that personal protective equipment ("PPE") requirements will not sufficiently protect farmworkers and their communities. Pet. Br. at 31. Petitioners also argue that EPA failed to adequately assess the risk to pollinators. *Id.* Finally, they argue that EPA failed to establish streptomycin's benefits. *Id.* at 31-32. Petitioners' arguments fail to demonstrate that EPA's decision should be held unlawful under FIFRA's highly deferential substantial evidence standard.

1. Substantial evidence in the administrative record supports EPA's assessment of the risk of increased antibiotic resistance in human pathogens through different exposure pathways.

Petitioners argue that the EPA's assessment of risks to human health from antibiotic resistance was deficient for two main reasons: (1) EPA allegedly "overlooked" the impacts of foliar application, Pet. Br. at 37; and (2) EPA allegedly "failed to accurately assess the heightened risk of exposure to streptomycin and streptomycin-resistant bacteria faced by

farmworkers and their communities" by assuming that personal protective equipment would adequately reduce risks of harm "despite contrary evidence." *Id.*

a. EPA assessed the risk that increased antibiotic resistance in human pathogens will develop through environmental pathways.

EPA conducted a qualitative risk assessment in order to assess the potential risk that the new use might lead to antibiotic resistance in human pathogens. EPA based this assessment on a Food and Drug Administration ("FDA") guidance document developed for veterinary uses, Guidance to Industry #152 (3-ER-332–367), but modified that guidance for plant agricultural antibiotic uses. Final Decision Notice at 10 (ER40); Safety Review at 3 (3-ER-286).

EPA's risk assessment consisted of three prongs. A release assessment considered the potential for release based on use pattern, target susceptibility, spectrum of activity, resistance mechanisms, and selection pressure. Safety Review at 3-6 (3-ER-286–289). An exposure assessment considered the potential for exposure of human pathogens. *Id.* at 6-7 (3-ER-289–290). And a consequence assessment considered the impacts of human pathogens developing resistance to streptomycin and

losing its efficacy for human clinical use. *Id.* at 8 (3-ER-291). *See generally* Final Decision Notice at 10-12 (1-ER-42–44). Although the summary of the exposure prong in the Final Decision Notice focuses primarily on "potential human exposure to bacteria of human health concern from either consumption of a treated commodity or by working in treated fields," Final Decision Notice at 10, 11-12 (1-ER-42, 43–44), EPA did consider the potential for resistance to develop from exposure through other environmental pathways. *See* Safety Review at 7 (3-ER-290) (observing that "plant agriculture use has a much greater environmental exposure [than animal use] due to the application by air blast and other spray technologies").

Contrary to Petitioners' argument, EPA did not "dismiss[] the risk of human exposure to streptomycin-resistant bacteria through environmental pathways." *See* Pet. Br. at 40. Rather, EPA considered the limited data available "for or against the presence of microbes of human health concern in the plant agriculture environment" and determined that the available information supported the assessment that while "plant agricultural use exposes more diverse bacterial populations … [it] may have less direct impact on bacteria of human health concern since

the human pathogens are a relatively minor component of the general agricultural environment (unless improperly handled animal manures are used in treated fields)." Safety Review at 7 (3-ER-290); ARRT Response to Comments at 2 (2-ER-182). Based on this assessment, EPA concluded that concerns of antibiotic resistance in human pathogens "come[] 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, not the environmental strains with resistance traits themselves." Safety Review at 7 (3-ER-290). Petitioners are thus incorrect to assert that EPA "overlook[ed] the potential spread of streptomycin resistance through environmental pathways," Pet. Br. at 37. EPA did look at the potential spread of streptomycin resistance through environmental pathways; it merely came to a conclusion based on its review of the available evidence with which Petitioners disagree.

Petitioners criticize EPA for relying on FDA's Guidance to Industry #152 as EPA's "sole tool" for assessing potential antibiotic resistance. *Id.* at 39. That critique also misses the mark. First, as Petitioners acknowledge, *id.* at 40, EPA adapted the existing framework in the FDA guidance to support EPA's own assessment of the risks of antibiotic

resistance developing in human pathogens from the new use of streptomycin on citrus crop group 10-10. *See, e.g.*, Final Decision Notice at 10, 12 (1-ER-42, 44) (noting that EPA adapted FDA's Guidance to Industry #152 to allow for assessment of "potential exposure to agricultural workers in treated fields or mixing, loading[,] or applying antibiotics"); Safety Review at 7 (3-ER-290) (noting that EPA adapted the exposure analysis to address environmental pathways from the agricultural scenario that do not align with the veterinary and animal husbandry scenario); ARRT Response to Comments at 3–5 (2-ER-183–185) (discussing various ways EPA adapted the FDA guidance to better suit assessing risks antibiotic resistance in human pathogens from use of antibiotics in plant agriculture).

In addition to this adaptation of FDA's Guidance to Industry #152, EPA took numerous steps to mitigate the potential risk of antibiotic resistance developing in human pathogens. As detailed in Argument I.A.1, *supra*, EPA required resistance management plans, monitoring, and annual sales reports. Final Decision Notice at 16-17 (1-ER-48–49). EPA also required mitigation measures that specifically address potential antibiotic resistance. *Id.* at 14, 19-20 (1-ER-46, 51–52). For

example, as part of EPA's approval, the label limits the potential pathway of exposure through spray drift, Pet. Br. at 41, by requiring applicators to direct spray into the canopy and to turn off outward pointing nozzles when spraying outer rows. Final Decision Notice at 19-20 (1-ER-51–52). The label limits the potential pathway of exposure "through residues in soil," Pet. Br. 41, by prohibiting reentry into treated areas for 12 hours. Final Decision Notice at 19-20 (1-ER-51–52). And, the label limits the potential pathway of exposure through "boots, tools, work clothes, and skin of family members who handle pesticides or work in areas where they are applied and then return home," Pet. Br. 41, by requiring applicators to wear personal protective equipment. Final Decision Notice at 20 (1-ER-52).[5]

Petitioners also argue that even if there are few human pathogens in citrus groves, plant bacteria that develop streptomycin resistance "can be spread through air, water, soil, and insect vectors," "come into contact with off-field human pathogens, and then transfer resistance to those off-field human pathogens." Pet. Br. at 43. EPA acknowledged that bacteria

[5] EPA responds below to Petitioners' arguments about the reentry prohibition and the personal protective equipment requirements.

with streptomycin resistance are common, and that some studies indicate there can be "horizontal gene transfer between bacterial species." ARRT Response to Comments at 2 (2-ER-182). However, despite decades of antibiotic use in agriculture, including streptomycin use on citrus under various emergency exemptions since 2016, there is no evidence in the record demonstrating that this has led "to the presence of antibiotic resistance in bacteria of human health concern." *Id.* at 2-3 (2-ER-182–183).

b. EPA addressed the risk that increased antibiotic resistance in human pathogens will develop through direct exposure of agricultural workers.

As described above, in order to reduce the risk that antibiotic resistance may develop in human pathogens through agricultural workers' exposure to streptomycin, EPA required that the label for streptomycin's new use include "additional Personal Protective Equipment (PPE) including a respirator, coveralls, protective headgear, and protective eyewear." *See* Final Decision Notice at 12, 20 (1-ER-44, 52). These protections are beyond what EPA typically requires for a conventional pesticide with the same quantitative risk profile.

Petitioners argue that EPA ignored the extent to which personal protective equipment will or will not actually be used, Pet. Br. at 45, and ignored evidence that that personal protective equipment will not address every exposure pathway. *Id.* at 51.

i. Personal protective equipment requirements are mandatory.

Petitioners argue that EPA relied on "a hypothetical, best case scenario," *id.* at 46, that "assumed that PPE requirements would sufficiently protect farmworkers and their communities." *Id.* at 31. But personal protective equipment use is not a hypothetical. Mandatory instructions on a pesticide product's labeling are not mere suggestions. EPA "is requiring, not assuming, that PPE be worn by users of the pesticide in order to be protective of potential effects on the user from exposure to the pesticide." EPA Response to Comments at 13 (2-ER-152); *see also* 7 U.S.C. § 136j(a)(2)(G) (making it unlawful "to use any registered pesticide in a manner inconsistent with its labeling"). The label requirements, including personal protective equipment requirements, are legally enforceable, and violations of label requirements are violations of Federal law. 7 U.S.C. § 136j(a)(2)(G); EPA

Response to Comments at 13 (2-ER-152). EPA therefore did consider "how the pesticide will actually be used." Pet. Br. at 46.

Petitioners point to surveys "documenting substantial noncompliance with personal protective equipment requirements," *id.* at 45, but as EPA explained, risk assessments reflect label requirements and "do not address misuse." EPA Response to Comments at 13 (2-ER-152). Petitioners argue that EPA's position is foreclosed by *National Family Farm Coalition v. EPA*, 960 F.3d 1120 (9th Cir. 2020). Pet. Br. at 48. In that case, this Court faulted EPA for failing to acknowledge the risk of noncompliance with the label. 960 F.3d at 1139, 1144. But in that case there was evidence of noncompliance with the label at issue, *id.* at 1139-42, which the Court noted was particularly "complex and onerous." *Id.* at 1140. One commenter complained that "[t]here doesn't appear to be any way for an applicator to be 100% legal in their application," *id.* at 1140, and the Office of Indiana State Chemist observed that the "label directions have been extremely challenging for a trained applicator to comply with completely." *Id.* at 1141. In contrast, Petitioners can point to no such evidence in the record here. The surveys Petitioners cite are general in nature and do not provide any particular evidence of

noncompliance with a label similar to the labels at issue here. *See, e.g.*, Pet. Br. at 46 (citing survey of agricultural workers who "believed there was no need to wear PPE"); *see also* Comments from Earthjustice, March 19, 2019, at 12 (2-ER-216) (summarizing surveys). Without more, there is no way to tell whether Petitioners' cited surveys speak to widespread noncompliance with label requirements that would result in applications of streptomycin inconsistent with its label, or simply to a generalized reluctance to wear personal protective equipment.

EPA pointed out the need for the information underlying those surveys. *See* EPA Response to Comments at 13 (2-ER-152). In response, Plaintiffs point to *League of United Latin American Citizens v. Regan*, 996 F.3d 673 (9th Cir. 2021), for the proposition that an agency cannot ignore peer-reviewed studies that are available to the agency "even if the underlying data is not." *Id.* at 700; *see* Pet. Br. at 49. But as explained above, EPA did not ignore Petitioners' surveys. EPA reasonably questioned whether those surveys involved labels that required personal protective equipment tailored to the particular product, as is that case here. Petitioners did not answer that question in the administrative record, or in their brief before this Court.

Petitioners also argue that EPA should not have approved the amended registrations without seeking additional information about the personal protective equipment usage surveys, citing 40 C.F.R. § 152.112(c) (EPA can only approve registration applications if no additional data needed) and § 158.75 (additional data requirements will be imposed if data is insufficient). Pet. Br. at 50. However, EPA's FIFRA regulations explicitly state that they do not restrict how EPA uses or evaluates the data and information in its risk assessment and risk management decisions, or the regulatory determinations that may be based upon the data. *See* 40 C.F.R. § 158.1(b)(3). Furthermore, EPA has the flexibility to determine what data requirements are necessary on a case-by-case basis. *See Id.* § 158.30(a) ("EPA has the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review.").

EPA concluded that the "streptomycin database is considered to be complete to assess risk to the environment and human health." Final

Decision Notice at 17 (1-ER-49). The Court should uphold EPA's conclusion regarding the streptomycin database.

ii. Mandatory personal protective equipment requirements are likely to reduce the risk of increased antibiotic resistance in human pathogens through direct exposure of agricultural workers.

Petitioners next argue that even when used according to the label, the personal protective equipment requirements do not address all "likely exposure scenarios." Pet. Br. at 54. In particular, Petitioners note that the label requires personal protective equipment only when applying or handling streptomycin, and prohibits reentry into sprayed areas for 12 hours, but the label does not require personal protective equipment for workers who reenter sprayed areas after 12 hours have elapsed. Pet. Br. at 51-52. Petitioners also argue that although EPA addressed the risk of workers' allergic reactions, EPA did not address the risk of workers acquiring resistant infections. *Id.* at 52.

No one adequately raised these concerns to EPA during the registration process. *See, e.g.*, Comments from Earthjustice, March 19, 2019, at 11-14 (addressing occupational exposure and "allergic reactions based on dermal or eye exposure" but not the reentry period) (2-ER-215–

218); Comments from Center for Biological Diversity, January 18, 2019, at 13 (asserting that EPA did not address "the potential for misuse" of the personal protective equipment requirements) (2-ER-234). It is well-settled that "a party's failure to make an argument before the administrative agency in comments on a proposed rule bar[] it from raising that argument on judicial review." *Universal Health Servs., Inc. v. Thompson*, 363 F.3d 1013, 1019 (9th Cir. 2004).

Even if this argument is not forfeited, it fails. The reentry interval will reduce potential exposure leading to resistance in human pathogens, because human pathogens are a relatively minor component of the general agricultural environment. *See* ARRT Response to Comments at 2 (2-ER-182). Furthermore, streptomycin has been used in plant agriculture since the 1950s, with no such effects reported. EPA thoroughly evaluated the potential risks and the Court should defer to EPA's judgment on matters within EPA's expertise such as the appropriate requirements for personal protective equipment.

2. Substantial evidence in the administrative record supports EPA's assessment of the risks to pollinators.

As noted above, EPA received and reviewed all pollinator data submitted by the registrants as required by 40 C.F.R. § 158.630. From the acute contact toxicity study, EPA observed that "[n]o effects were reported at 100 µg ai/bee in a honey bee contact study" and that "streptomycin is classified as practically nontoxic to honey bees on an acute exposure basis." Environmental Fate and Effects Division Assessment at 4 (3-ER-371); *see also* EPA Response to Comments at 18-19 (2-ER-157–158).

Petitioners argue that EPA's analysis was deficient for two reasons: (1) EPA allegedly did not determine the data were complete before granting the registration amendments, Pet. Br. at 56-58; and (2) EPA allegedly failed to follow its Pollinator Process Guidance without explanation. *Id.* at 59-61.

However, EPA *did* determine that the data were complete before granting the registration amendments. EPA agrees that it must "determine whether the available data are complete before, not after," approving a new use. *Id.* at 56-58 (citing *Pollinator Stewardship Council*,

806 F.3d at 523). Petitioners' contention is that EPA issued the challenged registration amendments "despite conceding that it had only 'limited' and 'incomplete' data about the pesticide's effects on pollinators." Pet. Br. at 58 (citations omitted). But Petitioners are misconstruing EPA's findings, although some of EPA's language is admittedly unclear. EPA does state in several places that "the pollinator data are incomplete," *see, e.g.*, Final Decision Notice at 3 (1-ER-35), Environmental Fate and Effects Division Assessment at 2 (3-ER-369), and that there was "limited pollinator data," *see, e.g.*, Environmental Fate and Effects Division Assessment at 9 (3-ER-376). However, these statements refer to data that EPA might require for the registration review, which covers all pesticide products that contain streptomycin, not to the data required for the amended registrations at issue here. EPA was referring to the ongoing registration review when it stated that it was "currently determining whether additional pollinator data are needed for streptomycin." Final Decision Notice at 4 (1-ER-36). In contrast, when EPA stated that it considered "[t]he streptomycin database … to be complete to assess risk to the environment and human health, when using [EPA's] standard processes," *id.* at 17 (1-ER-49), EPA

was referring to the pollinator data required to act on the registration amendments at issue.

Furthermore, EPA *followed* its Pollinator Process Guidance. Contrary to Petitioners' assertion, Pet. Br. at 59, EPA followed precisely the course of action it laid out for new additional outdoor uses of conventional pesticides such as streptomycin. *See* Pollinator Process Guidance at 15-16 (SER-154–155). As set forth in the flowchart provided in Appendix 1 of that guidance, this action was a registration action that was not for a new active ingredient or first outdoor use of an existing active ingredient but was a new outdoor use requiring review that was received before publication any rule amending the pollinator data requirements. *See id.* at 16 app. 1 (SER-155). In such circumstances, the guidance provides that EPA will conduct its review "with existing data" and additional data "will be called in under *registration review* criteria … ." *Id.* (emphasis added).

Petitioners are in essence seeking to compel EPA to make a scientific judgment that it has not yet made—that additional studies are necessary to support registration of all streptomycin products. As with any scientific assessment, EPA has acknowledged that there are

lingering uncertainties that could be resolved with additional data. Here, EPA noted that certain emerging areas of potential risk—such as impacts to bee gut biomes—might warrant further attention and be resolved by submission of additional data. EPA Response to Comments at 18-19 (2-ER-157–158). EPA may decide to issue a data call-in for such data during registration review. However, EPA has not yet done so and, contrary to Petitioners' suggestion, Pet. Br. at 57-58, 40 C.F.R. § 158.75 is a tool that allows EPA to impose additional data requirements on registrants when needed to support a registration but it is not a commandment requiring EPA to eliminate every scientific uncertainty before issuing a registration.

3. Substantial evidence in the administrative record supports EPA's assessment that the benefits of streptomycin's use as a pesticide outweigh its limited risks.

Before granting the challenged registration amendments, EPA received and considered data submitted by the registrants detailing the potential benefits of the new use of streptomycin on citrus crop group 10-10. *See* Benefits Memo at 1 (3-ER-293). EPA also received and considered several studies from Petitioners during the notice and comment period on the proposed decision. EPA Response to Comments at 28 (2-ER-167);

BEAD Response to Comments at 7-8 (2-ER-175–176). Considering both the severity of the citrus greening and citrus canker and the data presented by the registrants and commenters, EPA determined that there were benefits to the registration amendments. *See* Final Decision Notice at 13-15 (1-ER-45–47).

Petitioners argue that EPA's analysis of the benefits lacks substantial record evidence for three reasons: (1) EPA lacked evidence to support the effectiveness of streptomycin on canker because the studies on which EPA relied did not examine the effect of using copper alone, Pet. Br. at 62-63; (2) EPA failed to address information (the Zhang study) that streptomycin is not effective at treating citrus greening disease; *id.* at 63-64; and (3) EPA failed to provide any data that would indicate streptomycin is effective in preventing these diseases in uninfected trees. *Id.* at 64-65. None of Petitioners' arguments merit overturning EPA's decision.

First, the study EPA relied upon to determine whether streptomycin is effective at treating citrus canker was not ambiguous, and provided EPA with information on how the product would work as applied. Petitioners argue that EPA relied on "only a single study of trials

that showed that streptomycin and copper, *when used together*, can mitigate the effects of that disease" and that this provides an inappropriate foundation for EPA's assessment because "copper is a known effective treatment for citrus canker" and the "absence of a control group showing the treatment effects" of each chemical alone makes it "impossible to determine which, *if any*, of the benefits observed in the study can be attributed to streptomycin." *Id.* at 62-63. However, Petitioners' arguments rest on a faulty premise because they fail to acknowledge a key fact: for control of citrus canker, EPA expects that streptomycin will generally be combined with copper and not merely applied alone to treat the disease. Benefits Memo at 2 (3-ER-294). Copper is a "known effective treatment for citrus canker." Pet. Br. at 62. Unfortunately, as noted above in Argument I.A.2, *supra*, copper is also phytotoxic, which means that its use results in a significant loss of value to the grower due to "fruit blemishes and reduced fruit quality." Benefits Memo at 7 (3-ER-299). The data provided to EPA supported EPA's conclusion that streptomycin would reduce the amount and frequency of copper applications, which also reduces the likelihood of copper-

resistance developing, while allowing a similar level of efficacy. *Id.* at 7-9 (3-ER-299–301).

Second, EPA did not fail to consider the Zhang study. Petitioners argue that EPA ignored the Zhang study, which Petitioners submitted during the notice and comment period on the proposed decision and which allegedly demonstrates that "streptomycin is ineffective as a treatment for citrus greening disease." Pet. Br. at 63. Specifically, Petitioners argue that the Zhang study "concluded that streptomycin … was 'not effective in eliminating or suppressing' citrus greening bacteria," yet EPA "dismissed the study." *Id.* However, EPA did consider the Zhang study. *See* BEAD Response to Comments at 8 (2-ER-176) (noting the Zhang study). EPA simply did not find the Zhang study persuasive counterevidence against the benefits of the proposed new use. The study was not definitively applicable to field conditions as it was conducted under laboratory conditions with newly grafted citrus scion rather than on the field with established trees. *Id.* And the study focused on streptomycin's effectiveness at treating citrus greening instead of addressing streptomycin's efficacy at managing the symptoms of the disease, which was the primary benefit identified by EPA. *See* Benefits

Memo at 6 (3-ER-298) (streptomycin is "likely to result in higher fruit yields and quality"); BEAD Response to Comments at 7 (2-ER-175) (streptomycin resulted in a "decline of premature fruit drop and distorted fruits on infected trees and increase in marketable citrus fruit yields thereby benefiting citrus growers").

Third, EPA agrees that the registrants did not submit any data to support a claim that streptomycin prevents infection. However, when EPA weighed the benefits and the risks of the proposed registration amendments, EPA did not consider streptomycin's potential efficacy in *preventing* disease as a benefit separate from managing the disease. *See* Benefits Memo at 5, 6, 9 (3-ER-297, 298, 301). Thus, Petitioners' complaint does not go to whether substantial evidence in the record supports EPA's decision. Instead, Petitioners have questioned whether the registrants have sufficient efficacy data to support this claim on their labels. Registrants must keep on hand sufficient data to support any efficacy claims made on their label, including the implied claim that these streptomycin products are effective at "prevent[ing] infection." *See* 7 U.S.C. § 136a(c)(5); 40 C.F.R. § 158.400(e) (Test Note 1). Whether registrants have adequate data to support these claims is an issue for

EPA's ongoing oversight of the registrations. EPA will work with the registrants to determine whether this claim is supported by adequate data to demonstrate that the products are not misbranded and to remove the claim from the labels if it is not so supported. *See* 7 U.S.C. §§ 136(q)(1)(a) (a pesticide is misbranded if its label bears any statement which is false or misleading in any particular), 136j(a)(1)(E) (making it unlawful to distribute or sell any pesticide that is misbranded).

Because substantial evidence in the record supports EPA's analysis of the new use's potential adverse effects, the Court should reject Petitioners' FIFRA arguments.

II. Remand Is The Appropriate Remedy To Allow EPA To Address Its Obligations Under The ESA.

A. The Historical Context For EPA's Effects Determinations For FIFRA Registration Decisions.

Because of the complexity of making effects determinations and completing consultations for pesticides, numerous pesticides have been approved and are available for use that have not undergone ESA review—namely, without EPA first undertaking effects determinations or, when appropriate, initiating consultation under the ESA. *See Wash. Toxics Coal. v. EPA*, 413 F.3d 1024 (9th Cir. 2005), *abrogation on other grounds recognized by Cottonwood Env't L. Ctr. v. U.S. Forest Serv.*, 789

F.3d 1075 (9th Cir. 2015). In similar cases, EPA acknowledged that it has a duty to make effects determinations and, if required, consult under ESA section 7 before registering a pesticide containing a new active ingredient similar to this one. *See id*. at 1028.

In recent years, EPA has worked with multiple agencies to establish scientifically valid frameworks for assessing potential impacts to listed species and designated critical habitats from registration actions. *See* Declaration of Jan Matuszko in Support of EPA's Motion for Remand Without Vacatur, Feb.1, 2022 ("Matuszko Decl.") ¶ 12 (SER-017–018). EPA worked with these agencies to establish a process for pesticide consultation under the ESA. *Id*. ¶ 13 (SER-018). Congress is aware of this dialogue and has requested that EPA report on consultation progress and streamline integration of ESA and FIFRA procedures. Agricultural Act of 2014, Pub. L. No. 113-79, 128 Stat. 649, 951 (2014) (Section 10013).

To this end, EPA began several "pilot" biological evaluations as a first step towards implementing recommendations provided by the National Academy of Science. *See* Matuszko Decl. ¶ 12 (SER-017–018). Subsequently, EPA, the Department of the Interior, and the Department

of Commerce signed a memorandum of agreement establishing an interagency working group—to include these and other federal agencies—tasked with providing recommendations to the agencies' leadership on improving the ESA consultation process for pesticides. *See id*. The Agriculture Improvement Act of 2018 ("2018 Farm Bill") (Pub. L. No. 115-334, 132 Stat 4490, 4915 (2018)) codified the interagency working group and the memorandum of agreement. Pursuant to section 10115 of the 2018 Farm Bill and FIFRA, 7 U.S.C. § 136a(c)(11), interagency working group reports were delivered to Congress in December 2019, June 2020, and June 2021. Matuszko Decl. ¶ 13 (SER-018).

B. EPA's Acknowledgment That It Did Not Make ESA Effects Determinations Supports Remand.

Agencies have inherent authority to reconsider past decisions and to revise, replace or repeal initial actions. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Voluntary remand is the preferred remedy for deficient agency decisions. As the D.C. Circuit has opined, "[a]dministrative reconsideration is a more expeditious and efficient means of achieving an adjustment of agency policy than is resort to the federal courts." *B.J. Alan Co. v. Interstate Com. Comm'n*, 897 F.2d

561, 562 n.1 (D.C. Cir. 1990) (citation omitted). That court explained that "[w]e commonly grant such [relief], preferring to allow agencies to cure their own mistakes rather than wasting the courts' and the parties' resources reviewing a record that both sides acknowledge to be incorrect or incomplete." *Ethyl Corp. v. Browner*, 989 F.2d 522, 524 (D.C. Cir. 1993).

In this case, EPA acknowledges that it has not made effects determinations for streptomycin or, if required, initiated consultation under the ESA. 16 U.S.C. § 1536(a)(2); Matuszko Decl. ¶ 15 (SER-019–021). EPA recognizes that it must determine that streptomycin either has "no effect" on ESA listed species or "may affect" those species. 50 C.F.R. § 402.14(a); *see Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 188 (D.C. Cir. 2017); *see also* Matuszko Decl. ¶ 18 (SER-026). If EPA reaches the latter determination, it must consult with one or both of the Services and obtain either biological opinions or concurrences in determinations that streptomycin is not likely to adversely affect listed species or critical habitats. *See* 50 C.F.R. §§ 402.13, 402.14, 402.46; Matuszko Decl. ¶ 10 (SER-016). These "effects determinations" must be made by EPA in the first instance. 50 C.F.R. §§ 402.14(a), 402.40(b).

On remand, EPA will undertake the necessary, ESA-specific analysis for the amended registrations. EPA needs significant data for that analysis, and that data will take time for the registrants to generate. *See* Matuszko Decl. ¶ 24 (SER-029). After EPA receives the data, EPA must review it to ensure that it is of useable quality. *Id.* EPA must also take into account its existing obligations for other chemicals under settlement agreements and other public commitments to complete effects determinations and, if necessary, draft and final biological evaluations. *See* Matuszko Decl. ¶¶ 23-24 (SER-027–029). EPA anticipates that it can complete the required effects determinations for the amended registrations no sooner than the fall of 2026. *Id.* ¶ 25 (SER-029). If necessary, EPA will initiate consultation with the Services at that time.

EPA's request for a remand is timely and made in good faith. EPA acknowledged the ESA defect to Petitioners and moved for a remand before Petitioners' merits brief was filed. Because the standard for voluntary remand is met, the registration amendments should be remanded to EPA. *See Cal. Cmtys.*, 688 F.3d at 992.

III. Vacatur Of The Registration Amendments Is Not Required During The Pendency Of The Remand.

The Court should leave in place the registration amendments while EPA satisfies its obligations under the ESA. EPA acknowledges legal error, but the equities weigh in favor of allowing continued use of streptomycin on citrus crops during the remand.

To determine whether vacatur is warranted in a particular case, the Court undertakes an equitable analysis. The Court weighs "the seriousness of the agency's errors against the disruptive consequences of an interim change that may itself be changed." *NRDC*, 38 F.4th at 51 (citations omitted). The Court also considers "the extent to which either vacating or leaving the decision in place would risk environmental harm." *Id.* at 51-52. And the Court examines "whether the agency would likely be able to offer better reasoning [and] … adopt the same rule on remand, or whether such fundamental flaws in the agency's decision make it unlikely that the same rule would be adopted on remand." *Id.* at 52. Here, all three factors support leaving the amended registrations in place on remand.

A. EPA's failure to make effects determinations is not so serious a deficiency when weighed against disruptive consequences as to warrant vacatur.

Although EPA did not make ESA effects determinations, EPA did consider the environmental and ecological effects of amending the streptomycin registrations before granting the amended registrations. EPA acknowledges its failure to make ESA effects determinations, but its analyses indicate that the risks presented by the use of streptomycin pursuant to the amended registrations are generally limited. Balanced against these risks is a substantial benefit to citrus growers: a method of managing devastating diseases that pose serious threats to the American citrus crop.

The facts here—the failure to comply with the ESA before amending the registration of a pesticide under FIFRA—are analogous to the facts in *Center for Biological Diversity*, 861 F.3d at 188-89, where the D.C. Circuit remanded a flawed FIFRA registration without vacatur. There, as here, EPA did not make effects determinations before issuing a registration for a pesticide under FIFRA. *Id*. The D.C. Circuit reasoned that "[n]otwithstanding the EPA's failure to make an effects determination and to engage in any required consultation, it did not

register [the pesticide cyantraniliprole] in total disregard of the pesticide's potential deleterious effects" because it had assessed the ecological risks for cyantraniliprole as part of the registration process. *Id.* at 188. That ecological risk assessment—while distinct from the statutorily required ESA analysis—was relevant to analyzing the seriousness of the failure to make effects determinations. *See id.*

So too here. EPA did not grant the registration amendments "in total disregard of the pesticide's potential deleterious effects" to non-target organisms. *Id.* Rather, as described above in Argument I.A.1, *supra*, EPA assessed the environmental effects of the new use of streptomycin as required by FIFRA, determined that the only risks of concern to non-target organisms were for mammals (on a chronic basis) and sensitive aquatic nonvascular plants.

EPA does not contest that any violation of its ESA obligations is a significant concern. EPA has acknowledged its struggles with meeting its ESA obligations for pesticides and has expended considerable resources working to better address those obligations. *See, e.g.*, EPA, Balancing Wildlife Protection and Responsible Pesticide Use: How EPA's Pesticide Program Will Meet Its Endangered Species Act Obligations (2022) (SER-

031–104). However, even significant errors do not necessarily require vacatur. *See, e.g.*, *Center for Biological Diversity*, 861 F.3d at 188-89; *Cal. Cmtys.*, 688 F.3d at 993-94; *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405-06 (9th Cir. 1995).

Weighed against EPA's failure to conduct effects determinations, vacating the amended registrations has the potential to disrupt citrus growers' management of citrus greening and citrus canker. Final Decision Notice at 4-5 (1-ER-36–37); Benefits Memo (3-ER-293–304). As described in Argument I.A.2, *supra*, streptomycin's use on citrus is important to growers because streptomycin reduces the diseases' adverse effects, such as tree decline, premature leaves and fruit drop, and small and distorted fruits. Benefits Memo at 1-2 (3-ER-293–294). Streptomycin also aids the management of citrus canker disease by providing an alternative to treatments based on copper alone, *id.* at 6-7 (3-ER-298–299) and is an effective tool to manage pest resistance. *Id.* at 5 (3-ER-297). Indeed, these streptomycin products are among the few tools citrus growers have to ameliorate the effects of these diseases. *See* Nesci Decl. ¶¶ 7-9, 20 (SER-005–007, 012); BEAD Response to Comments at 7 (2-ER-

175) (streptomycin benefits citrus growers by reducing premature fruit drop and distorted fruits and by increasing yields of marketable fruits).

Even if the Court were to EPA's analysis to be insufficient under FIFRA, EPA's consideration of the potential ecological impacts of the new uses of streptomycin authorized by the amended registrations is properly considered in weighing the seriousness of the ESA error here. *Ctr. for Biological Diversity,* 861 F.3d at 188. Under the circumstances, EPA's failure to make effects determinations does not render the registration approval "so crippled as to be unlawful," and thus deserving of vacatur. *Radio-Television News Dirs. Ass'n v. FCC*, 184 F.3d 872, 888 (D.C. Cir. 1999); *see also Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009) ("vacatur need not be the remedy for an invalidly adopted rule").

B. The risk of environmental harm from leaving the amended registrations in place is low.

Petitioners assert that the risk of environmental harm is great, because the amended registrations authorize the largest ever use of streptomycin, and because EPA's compliance with the ESA will take years. Pet. Br. at 72-74. Petitioners largely repeat their arguments as to why EPA's FIFRA analysis was flawed and ignore that fact that EPA has

already assessed the risks of the new streptomycin use and found those risks to be very limited. *See* Argument I.A.1, *supra*. Further, Petitioners ignore that streptomycin has been used for decades in agriculture, including use on citrus under various emergency exemptions since 2016, without any evidence that its use has caused environmental harm.

C. EPA could on remand approve the amended registrations.

Petitioners assert that vacatur is appropriate because they believe EPA cannot fully comply with the ESA on remand before the amended registrations expire, citing *National Family Farm Coalition*, 960 F.3d at 1145 and *Pollinator Stewardship Council*, 806 F.3d at 532. Pet. Br. at 75-77. But as *Pollinator Stewardship Council* makes clear, the inquiry is whether it is possible for EPA to adopt the "same rule" on remand—here, that means the use authorized by the amended registrations. 806 F.3d at 532.

EPA can adopt the same rule, and reaffirm the amended registrations for this use, if it concludes that the use allowed for by the amended registrations is consistent with the ESA. *Cf. Nat'l Fam. Farm*, 966 F.3d at 922 (describing ESA's procedural requirements, and that a "no effect" determination for a pesticide like the one made there does not

require further action or consultation). One possible way to adopt the same rule here is for EPA to make a "no effect" finding. *Id.*

CONCLUSION

For these reasons, this Court should remand without vacatur the decision to amend the registrations.

Dated: September 14, 2022
Corrected October 27, 2022

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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STATUTORY AND REGULATORY ADDENDUM

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United States Code Annotated
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Part I. The Agencies Generally
Chapter 7. Judicial Review (Refs & Annos)

5 U.S.C.A. § 701

§ 701. Application; definitions

Effective: January 4, 2011
Currentness

(a) This chapter applies, according to the provisions thereof, except to the extent that--

(1) statutes preclude judicial review; or

(2) agency action is committed to agency discretion by law.

(b) For the purpose of this chapter--

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include--

(A) the Congress;

(B) the courts of the United States;

(C) the governments of the territories or possessions of the United States;

(D) the government of the District of Columbia;

(E) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them;

(F) courts martial and military commissions;

(G) military authority exercised in the field in time of war or in occupied territory; or

(H) functions conferred by sections 1738, 1739, 1743, and 1744 of title 12; subchapter II of chapter 471 of title 49; or sections 1884, 1891-1902, and former section 1641(b)(2), of title 50, appendix; [1] and

(2) "person", "rule", "order", "license", "sanction", "relief", and "agency action" have the meanings given them by section 551 of this title.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 392; Pub.L. 103-272, § 5(a), July 5, 1994, 108 Stat. 1373; Pub.L. 111-350, § 5(a)(3), Jan. 4, 2011, 124 Stat. 3841.)

Notes of Decisions (995)

Footnotes

1 See References in Text note set out under this section.

5 U.S.C.A. § 701, 5 USCA § 701
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted Negative Treatment Vacated by U.S. v. Wabash Valley Service Co., S.D.Ill., June 08, 2006

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. § 136j

§ 136j. Unlawful acts

Currentness

(a) In general

(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to distribute or sell to any person--

(A) any pesticide that is not registered under section 136a of this title or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter;

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 136a of this title;

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 136w(c)(5) of this title;

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.

(2) It shall be unlawful for any person--

(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this subchapter;

(B) to refuse to--

(i) prepare, maintain, or submit any records required by or under section 136c, 136e, 136f, 136i, or 136q of this title;

(ii) submit any reports required by or under section 136c, 136d, 136e, 136f, 136i, or 136q of this title; or

(iii) allow any entry, inspection, copying of records, or sampling authorized by this subchapter;

(C) to give a guaranty or undertaking provided for in subsection (b) which is false in any particular, except that a person who receives and relies upon a guaranty authorized under subsection (b) may give a guaranty to the same effect, which guaranty shall contain, in addition to the person's own name and address, the name and address of the person residing in the United States from whom the person received the guaranty or undertaking;

(D) to use for the person's own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this subchapter which is confidential under this subchapter;

(E) who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a product registered under this subchapter for restricted use without giving the classification of the product assigned to it under section 136a of this title;

(F) to distribute or sell, or to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 136a(d) of this title and any regulations thereunder, except that it shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator;

(G) to use any registered pesticide in a manner inconsistent with its labeling;

(H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;

(I) to violate any order issued under section 136k of this title;

(J) to violate any suspension order issued under section 136a(c)(2)(B), 136a-1, or 136d of this title;

(K) to violate any cancellation order issued under this subchapter or to fail to submit a notice in accordance with section 136d(g) of this title;

(L) who is a producer to violate any of the provisions of section 136e of this title;

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 136e of this title, any records required to be maintained pursuant to this subchapter, any report filed under this subchapter, or any information marked as confidential and submitted to the Administrator under any provision of this subchapter;

(N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this subchapter;

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this subchapter;

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test;

(Q) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this subchapter;

(R) to submit to the Administrator data known to be false in support of a registration; or

(S) to violate any regulation issued under section 136a(a) or 136q of this title.

(b) Exemptions

The penalties provided for a violation of paragraph (1) of subsection (a) shall not apply to--

(1) any person who establishes a guaranty signed by, and containing the name and address of, the registrant or person residing in the United States from whom the person purchased or received in good faith the pesticide in the same unbroken package, to the effect that the pesticide was lawfully registered at the time of sale and delivery to the person, and that it complies with the other requirements of this subchapter, and in such case the guarantor shall be subject to the penalties which would otherwise attach to the person holding the guaranty under the provisions of this subchapter;

(2) any carrier while lawfully shipping, transporting, or delivering for shipment any pesticide or device, if such carrier upon request of any officer or employee duly designated by the Administrator shall permit such officer or employee to copy all of its records concerning such pesticide or device;

(3) any public official while engaged in the performance of the official duties of the public official;

(4) any person using or possessing any pesticide as provided by an experimental use permit in effect with respect to such pesticide and such use or possession; or

(5) any person who ships a substance or mixture of substances being put through tests in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties and from which the user does not expect to receive any benefit in pest control from its use.

CREDIT(S)

(June 25, 1947, c. 125, § 12, as added Pub.L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 989; amended Pub.L. 95-396, § 16, Sept. 30, 1978, 92 Stat. 832; Pub.L. 100-532, Title VI, §§ 601(b)(2), 603, Title VIII, § 801(g), (q)(2)(B), Oct. 25, 1988, 102 Stat. 2677, 2678, 2682, 2683; Pub.L. 102-237, Title X, § 1006(a)(7), (b)(3)(L) to (O), Dec. 13, 1991, 105 Stat. 1895, 1896.)

Notes of Decisions (32)

7 U.S.C.A. § 136j, 7 USCA § 136j
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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. § 136p

§ 136p. Exemption of Federal and State agencies

Currentness

The Administrator may, at the Administrator's discretion, exempt any Federal or State agency from any provision of this subchapter if the Administrator determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

CREDIT(S)

(June 25, 1947, c. 125, § 18, as added Pub.L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 995; amended Pub.L. 94-140, § 8, Nov. 28, 1975, 89 Stat. 754; Pub.L. 100-532, Title VIII, § 801(k), Oct. 25, 1988, 102 Stat. 2682; Pub.L. 102-237, Title X, § 1006(b)(1), (2), Dec. 13, 1991, 105 Stat. 1895.)

Notes of Decisions (9)

7 U.S.C.A. § 136p, 7 USCA § 136p
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

End of Document

Public Law 113-79
113th Congress

An Act

Feb. 7, 2014
[H.R. 2642]

To provide for the reform and continuation of agdcultural and other programs ofthe Department ofAgriculture through fiscal year 2018, and for other purposes'

Be it enacted by the Sertate and House gf \epresentatiues of the United States of America in Congress assembled,

Agricultural Act of 2014.

SECTION 1. SHORTTITLE; TABLE OF COI'I'TENTS.

(a) Snont Tmm.-This Act may be cited as the "Agricultural Act of 2074"

(b) Tenr,n oF CoNTENts.-The table of contents of this Act is as follows:

commodities to notify that purchaser of an investigation or pending enforcement action against a producer from whom the purchaser has purchased perishable agricultural commodities.

SEC. 10012. REPORT ON HONEY.

(a) Rnpont.-Not later than 180 days after the date of enactment of this Act, the Secretary, in consultation with perso-ns affected by the potential establishmenl of a Federal standard for the identity oi hon6y, shall submit to the Commissioner of Food and Dru-gs a report'describing how an appropriate Federal standard for the ideniity of honey would be in the interest of consumers, the honey industry, and United States agriculture.

(b)-CousmpRATIoNS.-In preparing the report requir-ed under subsection (a), the Secretary shalllake into consideration the March 2006, Standard of Identity citizens petition filed with the Food and Drug Administration, -including any current industry amendments orllarifications necessary to update that petition.

SEC. 10013. REPORTS TO CONGRESS.

(a) hv GpNpnar,.-Not later than 180 days and 1 year after the date of enactment of this Act, the Administrator of the Environmental Protection Agency and Secretaries of Commerce, Agriculture and the Interior shall iubmit to the Committees on Agriculture and Natural Resources of the House of Representatives and the Committees on Agriculture, Nutrition, and Forestry and Environment and Public-Works of the Senate, 2 reports that describe approaches and actions taken by the Environmental Protection Agency, the United States Fish and Wildlife Service, and the National Marine Fisheries Service-

(1) to implement recommendations, including qn -analysis of how any itlentified delays to implementation will be over-come, of the 2013 Expert-Report -authored by-tttg.,National Research Council of the National Academies entitled "Assessing Risks to Endangered and Threatened Species from Pesticides";

(2) to otherurise minimize delays in integrating-

(A) the pesticide registration and registration review requirements of sections -3 and 33 of the Federal Insecticide, Fuigicide, and Rodenticide Act (7 U.S.C. 136a, 136w-8); and

(B) the species and habitat protection processes described in sections 7 and 10 of the Endangered Species Act of 1973 (16 U.S.C. 1536, 1539); and

(3) to ensure public participation and transparency d^urilS the developmenti implementation, and evaluation of the approaches'to imptem^ent the recommendations contained in the report described in paragraph-(1).

(b) RiieuInEMENr Foli FINAT RppoRr.-In addition to the requit"-"nt-s of subsection (a), the frnal report submitted to ConEress under that subsection shall-

(1) inform Congress of specific actions that have been and will'be taken to idd.e.. t[e recommendations identified in subsection (a)(1), including an evaluation to establish that-

(A) the approachei utilize the best available science;

(B) reas6nable and prudent alternatives within biological opinions are technologically and economically fea-sible;

(C) reasonable and prudent measures are necessary and appropriate; and

(D) the agencies ensure publ-ic participation and transparencv in tLe development of reasonable and prudent altern.tiu"t and reasonable and prudent measures; and

(2) update the study and report iequired by-9ub;e-c-t1o1s (b) and (it of section tdtO of Priblic Law 100-478 (7 U.S'C' 136a note).

SEC. 10014. STAY OF REGULATIONS.

Not later than 60 days after the date of enactment of this Act. the Secietarv shall hf[the administrative stay imposed under ifr"'r"t" of the"Secretary entitled "Christmas Tree Promotion, ii"r"ui.tt, und Ittfot-ation Order; Slay of Regylations" and pubiirtt"a by the Department of Agriculture on November. L7,^2oIL i76-F"A: neg. liz+t), on the-ieg-ulations in subpart.A.of part tZt+ of ti1l6 7, Code of Federal Regulations, establishing an i"-a"rtiv-f""aed promotion, research, and information program for fresh-cut Christmas trees.

21 USC 346a note.

SEC. 10015. REGUI.ATION OF SI]LFT]RYL FLUORIDE.

Notwithstanding any other provision_ of_law,- the Administrator of tfre b-rwiron*""tut Protection Agency shall exclude nonpesticideal sources of fluoride from any aggregate exposure ass^essment ."q"ii"a under section 408 of tie Fe-i[eral Food, Drug, and Cosmetic ffi-itiC.S.C. 346a) when assessing tolerances associated with residues from the pesticide.

SEc.10016.LoCALFooDPRoDUcTIoNANDPROGRAMEVALUATION.

7 USC 2204h.

(a) IN Gervnnar,.-The Secretary shall-

(1) collect data on-

(A) the production and marketing of lo-cally or regionally produced agricultur-al food products; and

" (B) direct -and indirect regulatory -compliance costs affecting the production an-d maiketing of locally or regionally produced'agricultural food products;

iii facilitate inieragency collaboration and data sharing on programs relating to local and regional food systems;

(3) monitor-

'-' (Ai the effectiveness of programs designed to expand or facilitate local food s,ystems; and

- (B) barriers to loial and regional market access due to Federal regulation of small-scale production; and

(4) evaluate"the manner in which local food systems-

(A) contribute to improving community food security; and

(B) assist populations with limited access to healthy food.

(b) RpqurnBMENTS.-In carrying out this section, the Secretary shall, at a minimum-

if i"otte"t and distribute comprehensive reporting of prices and ,rolome of locaily or regionaliy produced agricultural food products;

' fZl conduct surveys and analysis and publish .-reports relati-ng to ttt. productlion, handling, distribution, retail sales, ;d ffi"d studies (including consumer purchasin-g^patterns) ;i-;t-;; lo.uliv oi t'"gio"allv'produced agricultural food products;

(3) evaluate the effectiveness of existing programs rn growing local and regional food systems, including-

AGRICULTURE IMPROVEMENT ACT OF 2018

Public Law 115–334
115th Congress

An Act

Dec. 20, 2018
[H.R. 2]

To provide for the reform and continuation of agricultural and other programs of the Department of Agriculture through fiscal year 2023, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Agriculture Improvement Act of 2018.

7 USC 9001 note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Agriculture Improvement Act of 2018".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

7 USC 9001 note.

SEC. 2. DEFINITION OF SECRETARY.

In this Act, the term "Secretary" means the Secretary of Agriculture.

TITLE I—COMMODITIES

Subtitle A—Commodity Policy

SEC. 1101. DEFINITION OF EFFECTIVE REFERENCE PRICE.

Section 1111 of the Agricultural Act of 2014 (7 U.S.C. 9011) is amended—

(1) by redesignating paragraphs (8) through (25) as paragraphs (9) through (26), respectively; and

(2) by inserting after paragraph (7) the following:

"(8) EFFECTIVE REFERENCE PRICE.—The term 'effective reference price', with respect to a covered commodity for a crop year, means the lesser of the following:

"(A) An amount equal to 115 percent of the reference price for such covered commodity.

"(B) An amount equal to the greater of—

"(i) the reference price for such covered commodity; or

"(ii) 85 percent of the average of the marketing year average price of the covered commodity for the

"(B) CONSULTATION WITH ATTORNEY GENERAL.—The Secretary shall consult with the Attorney General on the promulgation of regulations and guidelines under subparagraph (A).

"(2) REPORT.—The Secretary shall annually submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report containing updates on the implementation of this subtitle.

"(b) AUTHORITY.—Subject to subsection (c)(3)(B), the Secretary shall have sole authority to promulgate Federal regulations and guidelines that relate to the production of hemp, including Federal regulations and guidelines that relate to the implementation of sections 297B and 297C.

"(c) EFFECT ON OTHER LAW.—Nothing in this subtitle shall affect or modify—

"(1) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

"(2) section 351 of the Public Health Service Act (42 U.S.C. 262); or

"(3) the authority of the Commissioner of Food and Drugs and the Secretary of Health and Human Services—

"(A) under—

"(i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

"(ii) section 351 of the Public Health Service Act (42 U.S.C. 262); or

"(B) to promulgate Federal regulations and guidelines that relate to the production of hemp under the Act described in subparagraph (A)(i) or the section described in subparagraph (A)(ii).

7 USC 1639s.

"SEC. 297E. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated such sums as are necessary to carry out this subtitle.".

7 USC 1639o note.

SEC. 10114. INTERSTATE COMMERCE.

(a) RULE OF CONSTRUCTION.—Nothing in this title or an amendment made by this title prohibits the interstate commerce of hemp (as defined in section 297A of the Agricultural Marketing Act of 1946 (as added by section 10113)) or hemp products.

(b) TRANSPORTATION OF HEMP AND HEMP PRODUCTS.—No State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of the Agricultural Marketing Act of 1946 (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable.

SEC. 10115. FIFRA INTERAGENCY WORKING GROUP.

Section 3(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 13a(c)) is amended by adding at the end the following:

"(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 Act and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.);

"(II) Federal case law regarding the intersection of this Act 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 Act 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 the date of enactment of this paragraph, 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 the date of enactment of this paragraph, 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 Act; 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).".

SEC. 10116. STUDY ON METHYL BROMIDE USE IN RESPONSE TO AN EMERGENCY EVENT.

(a) DEFINITIONS.—In this section:

(1) EMERGENCY EVENT.—The term "emergency event" means a situation—

(A) that occurs at a location on which a plant or commodity is grown or produced or facility providing for the

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 155. Registration Standards and Registration Review (Refs & Annos)
Subpart C. Registration Review Procedures (Refs & Annos)

40 C.F.R. § 155.56

§ 155.56 Interim registration review decision.

Effective: October 10, 2006
Currentness

The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. A FIFRA 3(c)(2)(B) notice requiring the needed data or information may precede, accompany, or follow issuance of the interim registration review decision. The Agency will follow procedures in § 155.58 when issuing an interim registration review decision.

SOURCE: 50 FR 49001, Nov. 27, 1985; 51 FR 17716, May 14, 1986; 71 FR 45732, Aug. 9, 2006; 73 FR 75595, Dec. 12, 2008, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136a and 136w.

Current through Sept. 9, 2022, 87 FR 55639, except for 40 CFR § 52.220, which is current through Sept. 1, 2022. Some sections may be more current. See credits for details.

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Subchapter E. Pesticide Programs
Part 155. Registration Standards and Registration Review (Refs & Annos)
Subpart C. Registration Review Procedures (Refs & Annos)

40 C.F.R. § 155.57

§ 155.57 Registration review decision.

Effective: October 10, 2006
Currentness

A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA.

SOURCE: 50 FR 49001, Nov. 27, 1985; 51 FR 17716, May 14, 1986; 71 FR 45732, Aug. 9, 2006; 73 FR 75595, Dec. 12, 2008, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136a and 136w.

Current through Sept. 9, 2022, 87 FR 55639, except for 40 CFR § 52.220, which is current through Sept. 1, 2022. Some sections may be more current. See credits for details.

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Subchapter E. Pesticide Programs
Part 158. Data Requirements for Pesticides (Refs & Annos)
Subpart A. General Provisions

40 C.F.R. § 158.1

§ 158.1 Purpose and scope.

Effective: June 14, 2022
Currentness

(a) Purpose. The purpose of this part is to specify the kinds of data and information EPA requires in order to make regulatory judgments under FIFRA secs. 3, 4, and 5 about the risks and benefits of pesticide products. Further, this part specifies the data and information needed to determine the safety of pesticide chemical residues under FFDCA sec. 408.

(b) Scope.

(1) This part describes the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; support the reregistration of a pesticide product; support the maintenance of a pesticide registration by means of the data call-in process, e.g., as used in the registration review program; or establish or maintain a tolerance or exemption from the requirements of a tolerance for a pesticide chemical residue.

(2) This part establishes general policies and procedures associated with the submission of data in support of a pesticide regulatory action.

(3) This part does not include study protocols, methodology, or standards for conducting or reporting test results; nor does this part describe how the Agency uses or evaluates the data and information in its risk assessment and risk management decisions, or the regulatory determinations that may be based upon the data.

(c) Scope of individual subparts.

(1) Conventional pesticides. Subparts A, B, C, D, E, F, G, K, L, N, O, and R apply to conventional pesticides.

(2) Biochemical pesticides. Subparts A, B, E, R, and U apply to biochemical pesticides.

(3) Microbial pesticides. Subparts A, B, E, R, and V apply to microbial pesticides.

(4) Antimicrobial pesticides. Subparts A, B, C, D, E, R, and W of this part apply to antimicrobial pesticides.

Credits
[78 FR 26978, May 8, 2013; 87 FR 22474, April 15, 2022]

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

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

Current through Sept. 9, 2022, 87 FR 55639, except for 40 CFR § 52.220, which is current through Sept. 1, 2022. Some sections may be more current. See credits for details.

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Subchapter E. Pesticide Programs
Part 158. Data Requirements for Pesticides (Refs & Annos)
Subpart A. General Provisions

40 C.F.R. § 158.30

§ 158.30 Flexibility.

Effective: December 26, 2007
Currentness

(a) FIFRA provides EPA flexibility to require, or not require, data and information for the purposes of making regulatory judgments for pesticide products. EPA has the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. The Agency encourages each applicant to consult with EPA to discuss the data requirements particular to its product prior to and during the registration process.

(b) The Agency cautions applicants that the data routinely required in this part may not be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects to man or the environment. EPA may require the submission of additional data or information beyond that specified in this part if such data or information are needed to appropriately evaluate a pesticide product.

(c) This part will be updated as needed to reflect evolving program needs and advances in science.

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

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

Current through Sept. 9, 2022, 87 FR 55639, except for 40 CFR § 52.220, which is current through Sept. 1, 2022. Some sections may be more current. See credits for details.

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Part 158. Data Requirements for Pesticides (Refs & Annos)
Subpart E. Product Performance for Products Claiming Effectiveness Against Vertebrate Pests, Products with Prion–Related Claims, and Products for Control of Organisms Producing Mycotoxins (Refs & Annos)

40 C.F.R. § 158.400

§ 158.400 Product performance data requirements table.

Effective: July 8, 2013
Currentness

(a) General. Sections 158.100 through 158.130 describe how to use this table to determine the product performance 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. The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. Data are also required for the general use patterns of forestry use, residential outdoor use, and indoor use, which includes both food and nonfood uses.

(c) Key. CR=Conditionally required; NR=Not required; R=Required; EP=End-use product; MP=Manufacturing-use product; TEP=Typical end-use product.

(d) Table. The following table lists the data requirements that pertain to product performance. The table notes are shown in paragraph (e) of this section.

Table—Product Performance Data Requirements

Guideline Number	Data Requirement	Use Pattern									Test substance to support		Test Note No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Residential Outdoor	Indoor	MP	EP	
		Food Crop	Nonfood Crop	Food	Nonfood	Food Crop	Nonfood Crop						
810.2700	Products with prion-related claims	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	EP	1

	Efficacy of fungicides and nematicides												
93-16	Products for control of organisms producing mycotoxins	CR	NR	CR	NR	CR	NR	NR	NR	NR	NR	EP	1
	Efficacy of vertebrate control agents												
96-5	Avian toxicants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
96-6	Avian repellents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96-7	Avian frightening agents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96-9	Bat toxicants and repellents	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	EP	1
96-10	Commensal rodenticides	R	R	NR	NR	NR	NR	NR	R	R	TEP	EP	1
96-12	Rodenticides on farm and rangelands	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
95-13	Rodent fumigants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95-16	Rodent reproductive inhibitors	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95-17	Mammalian predacides	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1

(e) Test notes. The following notes appy to the data requirements table in paragraph (d) of this section.

1. The Agency has waived the requirement to submit product performance data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration.

2. [Reserved]

Credits
[78 FR 13507, Feb. 28, 2013; 78 FR 26978, May 8, 2013]

SOURCE: 72 FR 60957, Oct. 26, 2007; 87 FR 22475, April 15, 2022, unless otherwise noted.

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

Current through Sept. 9, 2022, 87 FR 55639, except for 40 CFR § 52.220, which is current through Sept. 1, 2022. Some sections may be more current. See credits for details.

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KeyCite Yellow Flag - Negative Treatment
Proposed Regulation

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 180. Tolerances and Exemptions for Pesticide Chemical Residues in Food (Refs & Annos)
Subpart B. Procedural Regulations

40 C.F.R. § 180.41

§ 180.41 Crop group tables.

Effective: January 5, 2021
Currentness

(a) The tables in this section are to be used in conjunction with § 180.40 to establish crop group tolerances.

(b) Commodities not listed are not considered as included in the groups for the purposes of paragraph (b), and individual tolerances must be established. Miscellaneous commodities intentionally not included in any group include globe artichoke, hops, peanut, and water chestnut.

(c) Each group is identified by a group name and consists of a list of representative commodities followed by a list of all commodity members for the group. If the group includes subgroups, each subgroup lists the subgroup name, the representative commodity or commodities, and the member commodities for the subgroup. Subgroups, which are a subset of their associated crop group, are established for some but not all crops groups.

(1) Crop Group 1: Root and Tuber Vegetables Group.

(i) Representative commodities. Carrot, potato, radish, and sugar beet.

(ii) Table. The following table 1 lists all the commodities included in Crop Group 1 and identifies the related crop subgroups.

Table 1—Crop Group 1: Root and Tuber Vegetables

Commodities	Related crop subgroups
Arracacha (Arracacia xanthorrhiza)	1C, 1D
Arrowroot (Maranta arundinacea)	1C, 1D
Artichoke, Chinese (Stachys affinis)	1C, 1D

Calamondin (Citrus mitisxCitrofortunella mitis)

Citrus citron (Citrus medica)

Citrus hybrids (Citrus spp.) (includes chironja, tangelo, tangor)

Grapefruit (Citrus paradisi)

Kumquat (Fortunella spp.)

Lemon (Citrus jambhiri, Citrus limon)

Lime (Citrus aurantiifolia)

Mandarin (tangerine) (Citrus reticulata)

Orange, sour (Citrus aurantium)

Orange, sweet (Citrus sinensis)

Pummelo (Citrus grandis, Citrus maxima)

Satsuma mandarin (Citrus unshiu)

(15) Crop Group 10–10. Citrus Fruit Group.

(i) Representative commodities. Orange or Tangerine/Mandarin, Lemon or Lime, and Grapefruit.

(ii) Commodities. The following is a list of all the commodities in Crop Group 10–10.

Table 1—Crop Group 10-10: Citrus Fruit Group

Commodities	Related crop subgroups
Australian desert lime, Eremocitrus glauca (Lindl.) Swingle.....	10-10B
Australian finger lime, Microcitrus australasica (F. Muell.) Swingle.....	10-10B
Australian round lime, Microcitrus australis (A. Cunn. Ex Mudie) Swingle.....	10-10B
Brown River finger lime, Microcitrus papuana Winters.....	10-10B
Calamondin, Citrofortunella microcarpa (Bunge) Wijnands.....	10-10A
Citron, Citrus medica L.....	10-10A

Citrus hybrids, Citrus spp. Eremocitrus spp., Fortunella spp., Microcitrus spp., and Poncirus spp	10-10A
Grapefruit, Citrus paradisi Macfad	10-10C
Japanese summer grapefruit, Citrus natsudaidai Hayata	10-10C
Kumquat, Fortunella spp	10-10B
Lemon, Citrus limon (L.) Burm. f	10-10B
Lime, Citrus aurantiifolia (Christm.) Swingle	10-10B
Mediterranean mandarin, Citrus deliciosa Ten	10-10A
Mount White lime, Microcitrus garrowayae (F.M. Bailey) Swingle	10-10B
New Guinea wild lime, Microcitrus warburgiana (F.M. Bailey) Tanaka	10-10B
Orange, sour, Citrus aurantium L	10-10A
Orange, sweet, Citrus sinensis (L.) Osbeck	10-10A
Pummelo, Citrus maxima (Burm.) Merr	10-10C
Russell River lime, Microcitrus inodora (F.M. Bailey) Swingle	10-10B
Satsuma mandarin, Citrus unshiu Marcow	10-10A
Sweet lime, Citrus limetta Risso	10-10B
Tachibana orange, Citrus tachibana (Makino) Tanaka	10-10A
Tahiti lime, Citrus latifolia (Yu. Tanaka) Tanaka	10-10B
Tangelo, Citrusxtangelo J.W. Ingram & H.E. Moore	10-10A, 10-10C
Tangerine (Mandarin), Citrus reticulata Blanco	10-10A
Tangor, Citrus nobilis Lour	10-10A
Trifoliate orange, Poncirus trifoliata (L.) Raf	10-10A
Uniq fruit, Citrus aurantium Tangelo group	10-10C
Cultivars, varieties and/or hybrids of these	

(iii) Table. The following Table 2 identifies the crop subgroups for Crop Group 10–10, specifies the representative commodities for each subgroup and lists all the commodities included in each subgroup.

Table 2—Crop Group 10-10: Subgroup Listing

Representative commodities	Commodities

Crop Subgroup 10-10A. Orange subgroup	
Orange or tangerine/mandarin	Calamondin; citron; citrus hybrids; mediterranean mandarin; orange, sour; orange, sweet; satsuma mandarin; tachibana orange; tangerine (mandarin); tangelo; tangor; trifoliate orange; cultivars, varieties, and/or hybrids of these.
Crop Subgroup 10-10B. Lemon/Lime subgroup	
Lemon or lime	Australian desert lime; Australian finger lime; Australian round lime; brown river finger lime; kumquat; lemon; lime; mount white lime; New Guinea wild lime; Russell River lime; sweet lime; Tahiti lime; cultivars, varieties, and/or hybrids of these.
Crop Subgroup 10-10C. Grapefruit subgroup	
Grapefruit	Grapefruit; Japanese summer grapefruit; pummelo; tangelo; uniq fruit; cultivars, varieties, and/or hybrids of these.

(16) Crop Group 11: Pome Fruits Group.

(i) Representative commodities. Apple and pear.

(ii) Commodities. The following is a list of all the commodities included in Crop Group 11:

Crop Group 11: Pome Fruits Group—Commodities

Apple (Malus domestica)

Crabapple (Malus spp.)

Loquat (Eriobotrya japonica)

Mayhaw (Crataegus aestivalis, C. opaca, and C. rufula)

Pear (Pyrus communis)

Pear, oriental (Pyrus pyrifolia)

Quince (Cydonia oblonga)

(17) Crop group 11–10. Pome Fruit Group.

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 A. General

50 C.F.R. § 402.02

§ 402.02 Definitions.

Effective: October 28, 2019
Currentness

Act means the Endangered Species Act of 1973, as amended, 16 U.S.C. 1531 et seq.

Action means all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas. Examples include, but are not limited to:

(a) actions intended to conserve listed species or their habitat;

(b) the promulgation of regulations;

(c) the granting of licenses, contracts, leases, easements, rights-of-way, permits, or grants-in-aid; or

(d) actions directly or indirectly causing modifications to the land, water, or air.

Action area means all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action.

Applicant refers to any person, as defined in section 3(13) of the Act, who requires formal approval or authorization from a Federal agency as a prerequisite to conducting the action.

Biological assessment refers to the information prepared by or under the direction of the Federal agency concerning listed and proposed species and designated and proposed critical habitat that may be present in the action area and the evaluation potential effects of the action on such species and habitat.

Biological opinion is the document that states the opinion of the Service as to whether or not the Federal action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

Conference is a process which involves informal discussions between a Federal agency and the Service under section 7(a)(4) of the Act regarding the impact of an action on proposed species or proposed critical habitat and recommendations to minimize or avoid the adverse effects.

Conservation recommendations are suggestions of the Service regarding discretionary measures to minimize or avoid adverse effects of a proposed action on listed species or critical habitat or regarding the development of information.

Critical habitat refers to an area designated as critical habitat listed in 50 CFR parts 17 or 226.

Cumulative effects are those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation.

Designated non-Federal representative refers to a person designated by the Federal agency as its representative to conduct informal consultation and/or to prepare any biological assessment.

Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

Director refers to the Assistant Administrator for Fisheries for the National Marine Fisheries Service, or his or her authorized representative; or the Director of the U.S. Fish and Wildlife Service, or his or her authorized representative.

Early consultation is a process requested by a Federal agency on behalf of a prospective applicant under section 7(a)(3) of the Act.

Effects of the action are all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are caused by the proposed action. A consequence is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur. Effects of the action may occur later in time and may include consequences occurring outside the immediate area involved in the action. (See § 402.17).

Environmental baseline refers to the condition of the listed species or its designated critical habitat in the action area, without the consequences to the listed species or designated critical habitat caused by the proposed action. The environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation in process. The consequences to listed species or designated critical habitat from ongoing agency activities or existing agency facilities that are not within the agency's discretion to modify are part of the environmental baseline.

Formal consultation is a process between the Service and the Federal agency that commences with the Federal agency's written request for consultation under section 7(a)(2) of the Act and concludes with the Service's issuance of the biological opinion under section 7(b)(3) of the Act.

Framework programmatic action means, for purposes of an incidental take statement, a Federal action that approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time, and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

Incidental take refers to takings that result from, but are not the purpose of, carrying out an otherwise lawful activity conducted by the Federal agency or applicant.

Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non-Federal representative prior to formal consultation, if required.

Jeopardize the continued existence of means to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.

Listed species means any species of fish, wildlife, or plant which has been determined to be endangered or threatened under section 4 of the Act. Listed species are found in 50 CFR 17.11–17.12.

Major construction activity is a construction project (or other undertaking having similar physical impacts) which is a major Federal action significantly affecting the quality of the human environment as referred to in the National Environmental Policy Act [NEPA, 42 U.S.C. 4332(2)(C)].

Mixed programmatic action means, for purposes of an incidental take statement, a Federal action that approves action(s) that will not be subject to further section 7 consultation, and also approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

Preliminary biological opinion refers to an opinion issued as a result of early consultation.

Programmatic consultation is a consultation addressing an agency's multiple actions on a program, region, or other basis. Programmatic consultations allow the Services to consult on the effects of programmatic actions such as:

(1) Multiple similar, frequently occurring, or routine actions expected to be implemented in particular geographic areas; and

(2) A proposed program, plan, policy, or regulation providing a framework for future proposed actions.

Proposed critical habitat means habitat proposed in the Federal Register to be designated or revised as critical habitat under section 4 of the Act for any listed or proposed species.

Proposed species means any species of fish, wildlife, or plant that is proposed in the Federal Register to be listed under section 4 of the Act.

Reasonable and prudent alternatives refer to alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction, that is economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat.

Reasonable and prudent measures refer to those actions the Director believes necessary or appropriate to minimize the impacts, i.e., amount or extent, of incidental take.

Recovery means improvement in the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the Act.

Service means the U.S. Fish and Wildlife Service or the National Marine Fisheries Service, as appropriate.

Credits

[73 FR 76286, Dec. 16, 2008; 74 FR 20422, May 4, 2009; 80 FR 26844, May 11, 2015; 81 FR 7225, Feb. 11, 2016; 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 (281)

Current through Sept. 9, 2022, 87 FR 55639, except for 40 CFR § 52.220, which is current through Sept. 1, 2022. 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. § 402.13

§ 402.13 Informal consultation.

Effective: October 28, 2019
Currentness

(a) Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non–Federal representative, designed to assist the Federal agency in determining whether formal consultation or a conference is required.

(b) During informal consultation, the Service may suggest modifications to the action that the Federal agency and any applicant could implement to avoid the likelihood of adverse effects to listed species or critical habitat.

(c) If during informal consultation it is determined by the Federal agency, with the written concurrence of the Service, that the action is not likely to adversely affect listed species or critical habitat, the consultation process is terminated, and no further action is necessary.

(1) A written request for concurrence with a Federal agency's not likely to adversely affect determination shall include information similar to the types of information described for formal consultation at § 402.14(c)(1) sufficient for the Service to determine if it concurs.

(2) Upon receipt of a written request consistent with paragraph (c)(1) of this section, the Service shall provide written concurrence or non-concurrence with the Federal agency's determination within 60 days. The 60–day timeframe may be extended upon mutual consent of the Service, the Federal agency, and the applicant (if involved), but shall not exceed 120 days total from the date of receipt of the Federal agency's written request consistent with paragraph (c)(1) of this section.

Credits
[73 FR 76287, Dec. 16, 2008; 74 FR 20423, May 4, 2009; 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 (16)

Current through Sept. 9, 2022, 87 FR 55639, except for 40 CFR § 52.220, which is current through Sept. 1, 2022. Some sections may be more current. See credits for details.

End of Document


KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted Prior Version Held Invalid Washington Toxics Coalition v. U.S. Dept. of Interior, Fish and Wildlife Service, W.D.Wash., Aug. 24, 2006

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 D. Counterpart Regulations Governing Actions by the U.S. Environmental Protection Agency Under the Federal Insecticide, Fungicide and Rodenticide Act (Refs & Annos)

50 C.F.R. § 402.40

§ 402.40 Definitions.

Effective: October 28, 2019
Currentness

The definitions in § 402.02 are applicable to this subpart. In addition, the following definitions are applicable only to this subpart.

(a) Alternative consultation agreement is the agreement described in § 402.45.

(b) Effects determination is a written determination by the U.S. Environmental Protection Agency (EPA) addressing the effects of a FIFRA action on listed species or critical habitat. The contents of an effects determination will depend on the nature of the action. An effects determination submitted under § 402.46 or § 402.47 shall contain the information described in § 402.14(c) and a summary of the information on which the determination is based, detailing how the FIFRA action affects the listed species or critical habitat. EPA may consider the following additional sections for inclusion in an effects determination:

(1) A conclusion whether or not the FIFRA action is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat and a description of any reasonable and prudent alternatives that may be available;

(2) A description of the impact of any anticipated incidental taking of such listed species resulting from the FIFRA action, reasonable and prudent measures considered necessary or appropriate to minimize such impact, and terms and conditions necessary to implement such measures; and

(3) A summary of any information or recommendations from an applicant. An effects determination shall be based on the best scientific and commercial data available.

(c) FIFRA action is an action by EPA to approve, permit or authorize the sale, distribution or use of a pesticide under sections 136–136y of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 et seq. (FIFRA). In any consultation under this subpart, EPA shall determine the nature and scope of a FIFRA action.

(d) Listed species is a species listed as endangered or threatened under section 4 of the Act.

(e) Partial biological opinion is the document provided under § 402.47(a), pending the conclusion of consultation under § 402.47(b), stating the opinion of the Service as to whether or not a FIFRA action is likely to jeopardize the continued existence of one or more listed species or result in the destruction or adverse modification of one or more critical habitats, and describing the impact of any anticipated incidental taking of such listed species resulting from the FIFRA action, reasonable and prudent measures considered necessary or appropriate to minimize such impact, and terms and conditions necessary to implement such measures.

(f) Service Director refers to the Director of the U.S. Fish and Wildlife Service or the Assistant Administrator for Fisheries for the National Oceanic and Atmospheric Administration.

(g) Service Representative is the person or persons designated to participate in advance coordination as provided in this subpart.

Credits
[84 FR 45018, Aug. 27, 2019; 84 FR 50333, Sept. 25, 2019]

SOURCE: 51 FR 19957, June 3, 1986; 69 FR 47759, Aug. 5, 2004, unless otherwise noted.

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

Current through Sept. 9, 2022, 87 FR 55639, except for 40 CFR § 52.220, which is current through Sept. 1, 2022. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 50. Wildlife and Fisheries
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Subchapter A
Part 402. Interagency Cooperation—Endangered Species Act of 1973, as Amended (Refs & Annos)
Subpart D. Counterpart Regulations Governing Actions by the U.S. Environmental Protection Agency Under the Federal Insecticide, Fungicide and Rodenticide Act (Refs & Annos)

50 C.F.R. § 402.46

§ 402.46 Optional formal consultation procedure for FIFRA actions.

Currentness

(a) Initiation of consultation. EPA may initiate consultation on a FIFRA action under this section by delivering to the Service a written request for consultation. The written request shall be accompanied by an effects determination as defined in § 402.40(b) and a list or summary of all references and data relied upon in the determination. All such references and data shall be made available to the Service on request and shall constitute part of the Service's administrative record for the consultation. The time for conclusion of the consultation under section 7(b)(1) of the Act is calculated from the date the Service receives the written request from EPA. Any subsequent interchanges regarding EPA's submission, including interchanges about the completeness of the effects determination, shall occur during consultation and do not extend the time for conclusion of the consultation unless EPA withdraws the request for consultation.

(b) Additional information determination. For an effects determination prepared without advance coordination under § 402.44, the Service may determine that additional available information would provide a better information base for the effects determination, in which case the Service Director shall notify the EPA Administrator within 45 days of the date the Service receives the effects determination. The notification shall describe such additional information in detail, and shall identify a means for obtaining that information within the time period available for consultation. EPA shall provide a copy of the Service Director's notification to any applicant. EPA may thereafter revise its effects determination, and may resubmit the revised effects determination to the Service. If EPA advises the Service it will not resubmit a revised effects determination to the Service, its initiation of consultation on the effects determination is deemed withdrawn.

(c) Service responsibilities.

(1) Within the later of 90 days of the date the Service receives EPA's written request for consultation or 45 days of the date the Service receives an effects determination resubmitted under paragraph (b) of this section, and consistent with section 7(b)(1) of the Act, the Service shall take one of the following actions:

(i) If the Service finds that the effects determination contains the information required by § 402.40(b) and satisfies the requirements of section 7(b)(4) of the Act, and the Service concludes that the FIFRA action that is the subject of the consultation complies with section 7(a)(2) of the Act, the Service will issue a written statement adopting the effects determination; or

(ii) The Service will provide EPA a draft of a written statement modifying the effects determination, which shall meet the requirements of § 402.14(i), and as modified adopting the effects determination, and shall provide a detailed explanation of the scientific and commercial data and rationale supporting any modification it makes; or

(iii) The Service will provide EPA a draft of a biological opinion finding that the FIFRA action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat, and describing any reasonable and prudent alternatives if available.

(2) If the Service acts under paragraphs (c)(1)(ii) or (c)(1)(iii) of this section, EPA shall, on request from an applicant, provide the applicant a copy of the draft written statement or draft biological opinion received from the Service. The Service shall at the request of EPA or an applicant discuss with EPA and the applicant the Service's review and evaluation under this section, and the basis for its findings. EPA and any applicant may submit written comments to the Service within 30 days after EPA receives the draft written statement or opinion from the Service unless the Service, EPA and any applicant agree to an extended deadline consistent with section 7(b)(1) of the Act.

(3) The Service will issue a final written statement or final biological opinion within 45 days after EPA receives the draft statement or opinion from the Service unless the deadline is extended under section 7(b)(1) of the Act.

(d) Opinion of the Secretary. The written statement or opinion by the Service under paragraphs (c)(1) or (c)(3) of this section shall constitute the opinion of the Secretary and the incidental take statement, reasonable and prudent measures, and terms and conditions under section 7(b) of the Act.

(e) Delegation of Authority for Service decisions. Any written statement modifying an effects determination or any biological opinion issued under this section shall be signed by the Service Director and such authority may not be delegated below the level of Assistant Director for Endangered Species (FWS) or Director of Office of Protected Resources (NOAA Fisheries).

SOURCE: 51 FR 19957, June 3, 1986; 69 FR 47759, Aug. 5, 2004, unless otherwise noted.

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

Notes of Decisions (2)

Current through Sept. 9, 2022, 87 FR 55639, except for 40 CFR § 52.220, which is current through Sept. 1, 2022. Some sections may be more current. See credits for details.

End of Document

CERTIFICATE OF SERVICE

I hereby certify that on October 27, 2022, the foregoing Corrected Brief for Respondents was served on all parties through this Court's electronic filing system.

/s/ *Daniel R. Dertke*
Daniel R. Dertke
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