PATTI GOLDMAN (WSB #24426)
Earthjustice
705 Second Avenue, Suite 203
Seattle, WA 98104
(206) 343-7340
(206) 343-1526 *[FAX]*
pgoldman@earthjustice.org

Attorney for Plaintiffs

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON

WASHINGTON TOXICS COALITION; NORTHWEST COALITION FOR ALTERNATIVES TO PESTICIDES; DEFENDERS OF WILDLIFE; NATURAL RESOURCES DEFENSE COUNCIL; CENTER FOR BIOLOGICAL DIVERSITY; PACIFIC COAST FEDERATION OF FISHERMEN'S ASSOCIATIONS; INSTITUTE FOR FISHERIES RESOURCES; and HELPING OUR PENINSULA'S ENVIRONMENT, Plaintiffs, v. UNITED STATES DEPARTMENT OF INTERIOR; UNITED STATES DEPARTMENT OF FISH AND WILDLIFE SERVICE; UNITED STATES DEPARTMENT OF COMMERCE; and NATIONAL MARINE FISHERIES SERVICE, Defendants.	Civ. No. COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Earthjustice
705 Second Ave., Suite 203
Seattle, WA 98104
(206) 343-7340

INTRODUCTION

1. This action challenges counterpart regulations promulgated by the Fish and Wildlife Service ("FWS") and the National Marine Fisheries Service ("NMFS") pursuant to the Endangered Species Act ("ESA"), and the FWS's and NMFS's entry into an Alternative Consultation Agreement pursuant to those regulations. Together, the counterpart regulations and Alternative Consultation Agreement delegate authority to the Environmental Protection Agency ("EPA") to conduct unilateral ESA Section 7 consultations, without any concurrence by the FWS or NMFS, for EPA pesticide registrations that authorize pesticide uses that may affect threatened and endangered species and their critical habitat. This delegation violates ESA Section 7 and is arbitrary, capricious, and contrary to the best available scientific information. This action also challenges FWS's and NMFS's failure to prepare an environmental impact statement assessing alternatives to and the full effects of the counterpart regulations, as required by the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4332.

PARTIES

2. Plaintiff Washington Toxics Coalition ("WTC") is a non-profit organization that is incorporated in the State of Washington and has its place of business in Seattle, Washington. WTC protects public health and the environment by eliminating toxic pollution. WTC promotes alternatives to toxic chemicals in homes, schools, workplaces, agriculture, and industry. WTC advocates policies, empowers communities, and educates people to create a healthy environment. It works to ensure that uses of pesticides authorized by EPA will not harm threatened and endangered wildlife, including birds, salmon, and steelhead. WTC has approximately 1,300 members. WTC members use the waters of Washington for recreation, fishing, and aesthetic pursuits. Their interests are currently impaired and will continue to be impaired by uses of pesticides that harm threatened and endangered species.

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(206) 343-7340

3. Plaintiff Northwest Coalition for Alternatives to Pesticides ("NCAP") is a non-profit organization that engages in public education and advocacy to promote alternatives to toxic pesticides and to protect the environment from the harmful effects of such pesticides. NCAP is incorporated in Oregon and has its principal place of business in Oregon. It works to ensure that uses of pesticides authorized by EPA will not harm threatened and endangered salmon and steelhead. NCAP has conducted and compiled research on the effects of pesticides on salmonids. NCAP has over 1,800 members. NCAP members use the waters of California, Oregon, Washington, and Idaho for recreation, fishing, and aesthetic pursuits. Their interests are currently impaired and will continue to be impaired by uses of pesticides that harm threatened and endangered salmon and steelhead.

4. Plaintiff Defenders of Wildlife ("Defenders") is a nonprofit wildlife conservation organization, incorporated and with its principal place of business in Washington, D.C. Defenders works to protect wildlife in natural habitats throughout the world and its activities include protecting threatened and endangered species from pesticides. In the late 1980s, Defenders brought a lawsuit to compel EPA to protect black-footed ferrets from strychnine. Defenders of Wildlife v. Administrator of EPA, 882 F.2d 1294 (8th Cir. 1989). In 2003, Defenders sued EPA for failing to bring its registration of fenthion, which has resulted in the deaths of numerous threatened and endangered birds, into compliance with the ESA and other statutes. Defenders of Wildlife v. Whitman, No. 02-02089 (ESH) (D.D.C. filed 2002). Defenders has approximately one million members and supporters throughout the United States and the world. Defenders' members engage in and obtain great enjoyment and benefit from observing, studying, and photographing wildlife, including threatened and endangered species, throughout the United States.

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(206) 343-7340

5. Plaintiff Natural Resources Defense Council ("NRDC") is a non-profit environmental membership organization with more than 550,000 members nationwide and more than 24,000 members in Washington State. NRDC maintains its headquarters in New York City and has additional offices in Washington D.C., Los Angeles, and San Francisco. NRDC works to protect endangered species from pesticides and to improve regulation of pesticides to protect species and public health. NRDC's members derive recreational, scientific, aesthetic, and cultural benefits from the existence of species in the wild and their interests are impaired when such species decline and become endangered or threatened. In 2003, NRDC brought a lawsuit seeking to compel EPA to comply with the ESA in connection with its registration of the herbicide atrazine and to ensure that atrazine will not jeopardize the survival of various threatened and endangered species, including the loggerhead turtle, leatherback turtle, green turtle, Kemp's ridley turtle, shortnose sturgeon, pallid sturgeon, and various freshwater mussels. NRDC v. EPA, No. RDB 03 CV 2444 (D. Md. filed 2003).

6. Plaintiff Center for Biological Diversity (the "Center") is a non-profit corporation with over 10,000 members and offices in San Diego, Idyllwild, and San Francisco, California; Portland, Oregon; Sitka, Alaska; Tucson and Phoenix, Arizona; and Silver City, New Mexico. The Center is dedicated to the preservation, protection, and restoration of biodiversity, native species, and ecosystems, including through enforcement of the ESA against EPA with respect to pesticides. In 2002, the Center brought a lawsuit seeking to compel EPA to ensure that its registration of numerous pesticides will not jeopardize the survival of the threatened red-legged frog, as required under the ESA. Center for Biological Diversity v. Whitman, No. C-02-1580 JSW (N.D. Cal. filed 2002). In 2004, the Center filed a lawsuit to compel EPA to consult on pesticides affecting the endangered Barton Springs salamander, see Center for Biological

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(206) 343-7340

Diversity v. Leavitt, No. 1:04-cv-00126-CKK (D.D.C. filed Jan. 2004). In July 2004 the Center published a comprehensive report on the EPA's failure to regulate pesticides harmful to endangered species. The Center's members and staff obtain educational, scientific research, moral, spiritual, and recreational benefits from the existence of threatened and endangered species.

7. Plaintiff National Wildlife Federation ("NWF") is the nation's largest non-profit conservation advocacy and education organization. NWF has more than four million members and supporters, and has affiliate organizations in 46 states and territories. NWF's mission is to educate, inspire, and assist individuals and organizations of diverse cultures to conserve wildlife and other natural resources and to protect the earth's environment in order to achieve a peaceful, equitable, and sustainable future. NWF has been working to conserve threatened, endangered, and other imperiled species since its founding in 1936.

8. Pacific Coast Federation of Fishermen's Associations ("PCFFA") is the largest organization of commercial fishermen on the west coast, with member organizations from San Diego to Alaska representing thousands of men and women in the Pacific fleet. Many of PCFFA's members' livelihoods depend upon fish as a natural resource and, until recent fisheries closures, they generated hundreds of millions of dollars in personal income to the region through commercial fishing.

9. Institute for Fisheries Resources ("IFR") is a non-profit corporation that constitutes the conservation arm of PCFFA. IFR works to prevent water pollution and other adverse environmental impacts that affect the ecological health of fisheries, and to prevent further loss of habitat supporting marine fisheries (including preventing further loss of fresh water habitat used by salmon and steelhead). IFR has approximately 850 supporting members,

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most of them commercial fishermen, whose livelihoods are directly or indirectly affected by the loss of salmonid habitat in Washington, Oregon, Idaho, and Northern California.

10. Helping Our Peninsula's Environment ("HOPE") is a non-profit organization devoted to protecting the Greater Monterey Peninsula's natural land, air, and water ecosystems using research, education, and advocacy. It has its principal place of business in Carmel, California. HOPE has over 700 members, who use and obtain significant benefits from the species that inhabit the Monterey Peninsula. HOPE's members are harmed by pesticides that degrade the Peninsula's natural ecosystems and that precipitate the decline of the wildlife, tree, and plant populations that depend on those ecosystems to survive.

11. Plaintiffs' members use and enjoy species' habitat for recreational, scientific, aesthetic, cultural, and commercial purposes. Plaintiffs' members derive, or, but for the threatened and endangered status of listed species, would derive, recreational, scientific, aesthetic, and commercial benefits from the existence of listed species through wildlife observation, study, photography, and recreational and commercial fishing. The past, present, and future enjoyment of threatened and endangered species by members of the plaintiff organizations has been and will continue to be irreparably harmed by the failure of the federal agencies, including EPA, FWS, and NMFS, to comply with their obligations under the ESA.

12. The U.S. Department of the Interior is responsible for administering the provisions of the ESA with regard to threatened and endangered terrestrial and freshwater species. FWS is the agency within the Department of Interior to whom the Secretary of Interior has delegated significant authority for administering the ESA.

13. The U.S. Department of Commerce is responsible for administering the provisions of the ESA with regard to threatened and endangered marine and anadromous species.

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NMFS is the agency within the Department of Commerce to whom the Secretary of Commerce has delegated significant authority for administering the ESA.

14. The Departments of Interior and Commerce promulgated the counterpart regulations, entered into the Alternative Consultation Agreement, issued the environmental assessment, and made the finding of no significant impact challenged in this action.

JURISDICTION

15. This action is brought pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

BACKGROUND

16. The counterpart regulations and Alternative Consultation Agreement delegate to EPA the authority to conduct unilateral informal consultations on pesticide registrations that may affect listed species and/or their critical habitat. To understand the marked departure from the ESA scheme, it is necessary to review the legal framework for conducting ESA Section 7 consultations, how that framework applies to EPA's pesticide registrations, and EPA's pervasive past violations of its Section 7 obligations. This complaint then describes the rulemaking and NEPA processes, the counterpart regulations, and the Alternative Consultation Agreement.

I. THE ESA SECTION 7 CONSULTATION FRAMEWORK

17. Under the ESA, the Secretaries of Interior and Commerce are charged with listing species as endangered or threatened. An endangered species is one that is "in danger of extinction throughout all or a significant portion of its range," 16 U.S.C. § 1532(6), and a threatened species is one that "is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range." Id. § 1532(20). The Secretary of Interior, acting through the U.S. Fish and Wildlife Service, is responsible for terrestrial and fresh water species, and the Secretary of Commerce, acting through NMFS, is responsible for marine

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(206) 343-7340

species, including anadromous fish. Id. §§ 1532(15), 1533.

18. Section 7 of the ESA is entitled, "Interagency cooperation." Section 7(a)(2) requires that "each federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency (hereinafter in this section referred to as an 'agency action') is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary . . . to be critical." Id. § 1536(a)(2).

19. The Act establishes an interagency consultation process to assist federal action agencies in complying with their substantive Section 7(a)(2) duty to guard against jeopardy to listed species or destruction or adverse modification of critical habitat. Under Section 7(a)(2), federal action agencies must consult with the appropriate expert fish and wildlife agency to determine whether their actions are likely to jeopardize listed species' survival or adversely modify designated critical habitat and if so, to identify ways to modify the action to avoid that result. See id.; 50 C.F.R. § 402.14. Section 7's consultation and jeopardy mandates extend to both threatened and endangered species.

20. In 1986, FWS and NMFS issued joint consultation regulations. The joint consultation regulations broadly define the scope of agency actions subject to consultation as "all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies," including "the promulgation of regulations". See 50 C.F.R. § 402.02 (definition of "action").

21. Agencies must consult on ongoing agency actions over which the federal agency retains, or is authorized to exercise, discretionary involvement or control. See, e.g., id. § 402.16

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705 Second Ave., Suite 203
Seattle, WA 98104
(206) 343-7340

(reinitiation of consultation). Agencies must also consult on ongoing agency actions "if a new species is listed . . . that may be affected by the identified action." Id.

22. Under the joint consultation regulations, an action agency must initiate consultation under Section 7 whenever it undertakes an action that "may affect" a listed species or critical habitat. See id. § 402.14(a). The pertinent regulation states:

> Each Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat. If such a determination is made, formal consultation is required, except as noted in paragraph (b).

Id. The sole exception (paragraph (b)) occurs where "the Federal agency determines, with the written concurrence of the Director [FWS or NMFS], that the proposed action is not likely to adversely affect any listed species or critical habitat." Id. § 402.14(b).

23. The joint consultation regulations distinguish between two types of consultation: informal and formal. If the action agency determines that an action "may affect," but is "not likely to adversely affect" the listed species or its critical habitat and if the pertinent Service concurs in writing in that determination, no formal consultation is required. The process of arriving at the "not likely to adversely affect" determination and obtaining the Service's concurrence is called informal consultation. During informal consultation, the Services may, and often do, suggest modification to the action that will avoid the "the likelihood of adverse effects to listed species or critical habitat." Id. § 402.13(b). Informal consultation is a give-and-take process through which the Service's can obtain a sufficient factual basis or modifications to concur in the action agency's "not likely to adversely affect" determination. Informal consultation does not conclude until the pertinent Service issues its written concurrence, and only then may the consultation be resolved without preparation of a biological opinion. If the Service does not concur, or if the action agency has determined that the action is "likely to adversely

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705 Second Ave., Suite 203
Seattle, WA 98104
(206) 343-7340

affect" the listed species, the agencies must conduct a formal consultation. Id. §§ 402.02, 402.14(a).

24. Although not specified in the joint consultation regulations, federal agencies have developed the practice of forgoing any consultation where the action agency determines that an action will have "no effect" on listed species or critical habitat. The action agencies do not seek the written concurrence of the Services in such "no effect" determinations.

25. Formal consultation is initiated upon written request from an action agency and culminates with the Service's issuance of a biological opinion. Id. § 402.02 (definition of "formal consultation"). The request to initiate formal consultation must include the action agency's assessment of the action's impacts on listed species and their habitat, including any cumulative effects, and must provide all relevant information about such impacts to the expert fish and wildlife agency. Id. § 402.14(c).

26. The end product of formal consultation is a biological opinion in which the Service determines whether the action is likely to jeopardize the survival and recovery of listed species or destroy or adversely modify the species' critical habitat. 16 U.S.C. § 1536(b). In order to make this determination, NMFS must review all relevant information and provide a detailed evaluation of the action's effects, including the cumulative effects of other activities in the area, on the listed species and critical habitat. 16 U.S.C. § 1536(b)(3)(A); 50 C.F.R. § 402.14(g)-(h). The action agencies and the Services have a statutory duty to use the best available scientific information in an ESA consultation. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(g)(8). If the Service determines that the action is likely to jeopardize the species or adversely modify its critical habitat, the biological opinion must specify reasonable and prudent alternatives that will avoid jeopardy. 16 U.S.C. § 1536(b); 50 C.F.R. § 402.14(h)(3). The

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Service must also formulate discretionary conservation recommendations to reduce or minimize the action's impacts on listed species or critical habitat. 50 C.F.R. § 402.14(g)(6).

27. Not only does a Section 7 consultation assist the action agency in discharging its duty to avoid jeopardy and adverse modification, but the biological opinion also may affect the action agency's obligation to avoid the "take" of listed species. Under ESA Section 9, 16 U.S.C. § 1538(a)(1)(B), it is illegal for any person – whether a private or governmental entity – to "take" any endangered species of fish or wildlife. By regulation, FWS and NMFS may make the take prohibition applicable to threatened species, which they generally have done. See 50 C.F.R. § 17.31(a); id. pt. 223. "Take" is defined to mean "harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct." Id. § 1532(19). FWS and NMFS have defined "harm" to include "significant habitat modification or degradation which actually kills or injures fish or wildlife by significantly impairing essential behavioral patterns, including breeding, spawning, rearing, migrating, feeding or sheltering." 50 C.F.R. § 222.102 (NMFS definition); accord id. § 17.3 (similar FWS definition).

28. As part of a consultation, the Service determines whether to authorize the incidental take of listed species through the issuance of an incidental take statement. An incidental take statement may be issued only if the action can proceed without causing jeopardy. 16 U.S.C. § 1536(b)(4). An incidental take statement must: (1) specify the impact of the incidental take on the listed species; (2) specify reasonable and prudent measures the Service considers necessary to minimize that impact; and (3) set forth mandatory terms and conditions to implement such reasonable and prudent measures. Id.

29. An incidental take statement insulates the federal agency from liability for a take of a threatened or endangered species, provided the agency complies with the statement's terms

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Seattle, WA 98104
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and conditions. This insulation extends further to any entity receiving a federal permit, license, authorization, or funding subject to, and in compliance with, the statement. Thus, the Act provides that:

> [A]ny taking that is in compliance with the terms and conditions specified in a written statement provided under subsection (b)(4)(iv) of this section shall not be considered to be a prohibited taking of the species concerned.

16 U.S.C. § 1536(o)(2).

II. EPA MUST ENSURE, THROUGH SECTION 7 CONSULTATION, THAT ITS PESTICIDE REGISTRATIONS ARE NOT LIKELY TO JEOPARDIZE LISTED SPECIES OR ADVERSELY MODIFY THEIR CRITICAL HABITAT.

30. EPA is the federal agency charged with registering pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. Under FIFRA, a pesticide may generally not be sold or used in the United States unless it has an EPA registration for specified uses of that particular pesticide. Id. § 136a(a). EPA may register a pesticide if it determines that the labeling submitted by the registrant complies with FIFRA's requirements and that the pesticide will not cause unreasonable adverse effects on health or the environment, including on threatened and endangered species and their habitat. Id. § 136a(c)(5). To make these determinations, EPA requires the registrants to submit data on the pesticide's effects. Id. § 136a(c)(2)(B). As part of a registration, EPA approves a label submitted by the registrant for each pesticide use.

31. FIFRA makes it unlawful to use a pesticide in a manner inconsistent with the label. Id. § 136j(2)(G). FIFRA also makes it unlawful to sell a misbranded pesticide. Id. § 136j(1)(E)-(F). A pesticide is misbranded if its label fails to contain warnings, cautionary statements, or directions necessary to protect the environment. Id. § 136(q). EPA's registration of the pesticide and approval of the label is not a defense to a misbranding charge or any other offense under FIFRA. Id. § 136a(f)(2).

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32. After approving a pesticide registration, EPA retains discretionary involvement and control over that registration. EPA must periodically review pesticide registrations with a goal of reviewing each pesticide registration every 15 years. Id. § 136a(g)(1). EPA has the authority to compel registrants to submit data necessary for a re-registration review. Id. § 136a(g)(2). In addition to such explicit data submission requirements, registrants must submit to EPA any information about registered pesticides' unreasonable adverse effects on health or the environment. Id. § 136d(a)(2). EPA must take such information into account in reviewing and, where necessary, modifying the pesticide registrations.

33. The EPA Administrator has the authority to cancel pesticide registrations whenever "a pesticide or its labeling or other material required to be submitted does not comply with the provisions of [FIFRA] or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." Id. § 136d(b). The Administrator may immediately suspend a pesticide registration to prevent an imminent hazard. Id. § 136d(c). An announcement by the Administrator of an intent to cancel a pesticide use often results in the registrant's voluntary cancellation of, or agreement to further constraints upon, that use.

34. Congress initially added environmental standards to FIFRA in 1972, and it has since amended FIFRA to strengthen those standards. To bring existing registrations into compliance with the current FIFRA standards, FIFRA establishes a re-registration process in which EPA requires the registrant to submit additional data and assesses the new data to determine whether the pesticide uses pass muster under the upgraded standards. Id. § 136a-1. The same standards that apply to new registrations govern registration determinations. Accordingly, as part of a re-registration determination, EPA is required to impose restrictions on

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uses of the pesticides that cause unreasonable health or environmental effects, including those uses that cause harm to threatened or endangered species. Congress first mandated this process in 1972, but, as of 1986, EPA had re-registered none of the tens of thousands of pesticides subject to re-registration, and had completed its reassessment of none of the 600 pre-1972 pesticide active ingredients. General Accounting Office, EPA's Formidable Task to Assess and Regulate Their Risks at 3 (1986). Congress amended FIFRA again in 1988 and 1996 to accelerate this process and establish deadlines for re-registering whole categories of pesticides. See 7 U.S.C. §§ 136a-1 & 136b. EPA is in the midst of the statutory schedule for re-registering pesticides that have been on the market for years and often decades prior to enactment of the environmental registration requirements currently in place.

35. Pesticide registrations are federal agency actions over which EPA maintains discretionary involvement or control. See 50 C.F.R. § 402.02. EPA can exercise that involvement and control, inter alia, through re-registration reviews and determinations, through the call-in of new data, through reclassification of pesticides and their formulations as restricted use pesticides, through cancellation notices, and through suspension actions. Both new and existing pesticide registrations, as well as other authorizations of pesticide use, constitute agency actions subject to Section 7 consultation under the joint consultation regulations where the pesticide use "may affect" listed species. Use of numerous pesticides in accordance with their current EPA registrations and EPA-approved labels "may affect" listed species and/or their critical habitat by causing direct mortalities, impairing essential life functions, diminishing food sources, and/or degrading habitat needed for the species' survival.

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III. EPA'S ABYSMAL ESA TRACK RECORD

A. EPA's Failure to Consult on Numerous Pesticide Registrations and Failure to Implement Those Consultations That It Did Complete

36. EPA's consultation history has been marked by fits and starts with little follow through and virtually no changes to pesticide registrations and labels. Initially, EPA pursued a case-by-case approach, consulting individually on newer pesticides to the exclusion of the older, often more toxic pesticides, but EPA concluded that this approach provided inadequate protection for listed species. 54 Fed. Reg. 27,984, 27,985 (1989).

37. EPA then shifted to a cluster approach in which EPA submitted all pesticides registered for the same use pattern for a grouped consultation. EPA pursued this approach to eliminate market inequities that could result from focusing on single pesticides rather than the entire group used for a common purpose. In the early to mid-1980s, EPA received biological opinions for clusters of pesticides used on selected crops, such as corn, soybeans, cotton, oats, barley, wheat and rye, and for particular purposes, such as forests and rangeland. 54 Fed. Reg. at 27,985.

38. In 1988, EPA issued a Federal Register notice proposing an endangered species protection program based on the cluster consultation approach. 53 Fed. Reg. 7716 (1988). In 1989, EPA proposed a different endangered species protection program that would prioritize consultations on the most vulnerable species and would eliminate consultation on low application rates that EPA determined would not affect listed species. 54 Fed. Reg. 27,984 (1989). EPA neither finalized this proposed program nor instituted any priority scheme for consultations on pesticide registrations.

39. EPA proposed to implement mitigation prescribed in biological opinions through label changes that would inform users that the product could be used only in compliance with

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county bulletins. Imposing restrictions by referring to such county bulletins would eliminate the need to modify labels to add or delete references to particular restrictions, geographies, or species. Violations of the label and county bulletin requirements would constitute a FIFRA violation. EPA has not finalized this program, but it re-proposed a similar endangered species protection program in December 2002. 67 Fed. Reg. 71,549 (Dec. 2, 2002).

40. In the various consultations conducted in the 1980s and early 1990s, FWS issued biological opinions on many dozens of pesticide registrations. See 54 Fed. Reg. at 27,985 (describing numerous jeopardy biological opinions issued by FWS in the 1980s). For example, in 1989, FWS issued its most recent biological opinion pertaining to aquatic species, which made jeopardy findings for numerous pesticides. When Fish and Wildlife Service made a jeopardy determination for any of the pesticides, it recommended a reasonable and prudent alternative to avoid jeopardy which typically included a pesticide-free buffer around the species' habitat to prevent interaction between the pesticide and the species. Even when FWS did not make a jeopardy finding, it routinely imposed no-spray buffers as binding reasonable and prudent measures and/or terms and conditions of its incidental take statement to reduce incidental take for many of the pesticide uses.

41. Despite issuance of this and several other biological opinions over a decade ago, EPA has not incorporated the buffers embodied in the reasonable and prudent alternatives or the incidental take statements into its pesticide registrations and approved labels. EPA has not implemented these measures even where it has completed re-registration for the pesticide. Instead, EPA has postponed implementation of the biological opinions and incidental take statements until it finalizes the endangered species program initially proposed in 1989. Illustrative of this routine practice, EPA stated in its 1996 trifluralin re-registration eligibility

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decision that it "is not imposing label modifications at this time. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program." Trifluralin Re-registration Eligibility Decision at 73 (April 1996).

B. EPA's Failure to Initiate Consultations on Pesticide Registrations Pending Finalization of an Endangered Species Program, Which It Has Not Done

42. Not only did EPA postpone implementation of the biological opinions and incidental take statements, but it also refrained from initiating consultations on numerous pesticide registrations until finalization of its endangered species protection program. It did so even when it was re-registering pesticides as part of its re-registration process. As part of that process, EPA conducted ecological risk assessments that assess whether the estimated environmental concentrations of the pesticide, when used in accordance with the approved registration and label, will exceed EPA's regulatory levels of concern established for select species based on toxicity studies. For many pesticides, EPA's risk assessments determined that estimated environmental concentrations exceed EPA's levels of concern for listed species or their habitat. In 1989, in describing its proposed endangered species program, EPA equated such exceedances with "may affect" determinations that trigger its Section 7 consultation obligation. 54 Fed. Reg. at 28,004.

43. EPA generated these risk assessments to make the FIFRA-mandated re-registration decisions. It has re-registered dozens of pesticides based on these assessments in the last 10 years. EPA completed these re-registrations without consulting on the pesticides' impacts on listed species where its risk assessments documented significant risks to those species. EPA postponed compliance with the ESA until it finalized an endangered species protection program proposed in 1989, as explained in this boilerplate language typically inserted in EPA re-registration decisions:

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> The Endangered Species Protection Program is expected to become final at sometime in the future. Limitations on the use of chlorothalonil may be required at that time to protect endangered and threatened species, but these limitations have not been defined and may be formulation-specific. EPA anticipates that a consultation . . . may be conducted in accordance with the species-based priority approach described in the Program. After completion of the consultation, registrants will be informed if any required label modifications are necessary.

Chlorothalonil Re-registration Eligibility Decision at 153 (April 1999).

C. Litigation Challenging EPA's Failure to Consult on its Pesticide Registrations

1. Washington Toxics Coalition v. EPA

44. In January 2001, the Washington Toxics Coalition, Northwest Coalition for Alternatives to Pesticides, Pacific Coast Federation of Fishermen's Associations, and Institute for Fisheries Resources filed a lawsuit seeking to compel EPA to consult on the impacts of certain pesticides on listed salmon and steelhead. Washington Toxics Coalition v. EPA, No. C01-132C (W.D. Wash.). The environmental and commercial fishing group plaintiffs provided specific evidence of harm from 55 pesticides based on evidence that these pesticides are getting into salmon waters at levels that cause harm to salmon or their habitat. First, the U.S. Geological Survey had found concentrations of 14 pesticides in salmon waters at levels that are associated with negative impacts on fish or other aquatic life. Second, EPA risk assessments had found that estimated environmental concentrations of these pesticides from registered uses would exceed EPA's levels of concern for salmon, their food supply, or their habitat.

45. In 2002, a U.S. District Court in Seattle held that "it is undisputed that EPA has not initiated, let alone completed, consultation with respect to the relevant 55 pesticide active ingredients" and that "EPA's own reports document the potentially-significant risks posed by registered pesticides to threatened and endangered salmonids and their habitat." According to the court:

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> NMFS listed the Sacramento winter run Chinook in 1989. During the 1990s, NMFS listed as threatened or endangered approximately 25 additional salmonids. Despite competent scientific evidence addressing the effects of pesticides on salmonids and their habitat, EPA has failed to initiate section 7(a)(2) consultation with respect to its pesticide registrations. . . . Such consultation is mandatory and not subject to unbridled agency discretion. The Court declares, as a matter of law, that EPA has violated section 7(a)(2) of the ESA with respect to its ongoing approval of 55 pesticide active ingredients and registration of pesticides containing those active ingredients.

Washington Toxics Coalition v. EPA, No. C01-132C, Order (W.D. Wash. July 2, 2002). The court ordered EPA to initiate consultations on 55 pesticides according to a schedule that runs through December 1, 2004.

46. Because initiation of consultation with NMFS merely starts the Section 7 process and on-the-ground protections may take years, the plaintiffs asked the court to impose interim measures to protect listed salmon and steelhead from these pesticides during the consultation process. By order issued on January 22, 2004, the court imposed 20-yard ground and 100-yard aerial buffers along salmon supporting waters. These buffers are drawn from the low end of the buffers prescribed in the 1989 Fish and Wildlife Service biological opinion for aquatic species and in the county bulletins EPA has developed in partial implementation of that biological opinion. The court found that pesticide-application buffer zones are "a common, simple, and effective strategy to avoid jeopardy to threatened and endangered salmonids" and that they will "substantially contribute to the prevention of jeopardy." Order at 16, 18 (Aug. 8, 2003). The court also required public warnings in urban home and garden stores on products containing seven pesticides frequently detected in urban salmon streams by the U.S. Geological Survey. Both EPA and the industry-intervenors have appealed the injunction to the Ninth Circuit.

47. EPA has been making effects determinations according to the schedule imposed by the court in Washington Toxics Coalition v. EPA. To date, NMFS has not completed any

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consultations, formal or informal, on the pesticides at issue in Washington Toxics Coalition. However, in April 2004, NMFS circulated a draft nonconcurrence letter, which disagrees with the numerous "not likely to adversely affect" determinations that EPA has made thus far. The letter states that the pesticide uses "may have greater than discountable or insignificant effects on listed species" and "determined that the proposed action is 'likely to adversely affect' the 26 ESUs [evolutionarily significant units comprising the listed salmon and steelhead] and thus, requires formal consultation." Draft Nonconcurrence Letter at 1. More specifically, the draft nonconcurrence letter concludes that EPA's risk assessments do not constitute the best available science because: (1) they are not based on the available peer reviewed scientific literature; (2) they focus on active ingredients to the exclusion of inert ingredients, additives, and the full range of uses of the products; (3) they are devoid of critical information about the locations and needs of the listed salmon species; (4) they lack information about critical exposures, such as those from residential uses and cumulative exposures; and (5) they fail to incorporate evidence of probable sublethal effects. Id. at 2-3. Without this information, NMFS states that it cannot evaluate the pesticides' impacts on listed salmon and can have no assurance that the pesticide uses will not cause serious risks and adverse effects. Id. at 3-4.

48. By letter dated July 26, 2004, the Washington Toxics Coalition plaintiffs provided notice to EPA of their intent to challenge the "no effect" and "not likely to adversely affect" determinations made thus far by EPA because they are based on an inadequate scientific record and a flawed and incomplete assessment of the pesticides' effects. The notice letter echoes the concerns raised in NMFS's draft nonconcurrence and provides examples of flawed effects determinations where, for example, EPA lacks both the data and scientific methods to assess exposures to species from urban uses and EPA routinely assumes impacts will be minor even

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though it lacks accurate data on the species' locations and needs and on pesticide usage in the species' habitat.

2. Other Litigation Seeking Section 7 Consultation on Pesticide Registrations

49. EPA's failure to consult on pesticide registrations' impacts on listed species extends beyond the pesticides and species at issue in Washington Toxics Coalition. Several other lawsuits similarly seek to compel EPA to comply with its Section 7 consultation obligations, including the Center's 2002 lawsuit to compel EPA to consult on pesticide registrations that affect the threatened red-legged frog, see Center for Biological Diversity v. Whitman, No. C-02-1580 JSW (N.D. Cal. filed 2002), Defenders' 2002 lawsuit to stop EPA from authorizing uses of fenthion that kill threatened and endangered birds, see Defenders of Wildlife v. Whitman, No. 02-02089 (ESH) (D.D.C. filed 2002); NRDC's 2003 lawsuit to compel EPA to consult to ensure that its atrazine registration will not affect threatened and endangered sea turtles, sturgeon, and freshwater mussels, see NRDC v. EPA, No. RDB 03 CV 2444 (D. Md. filed 2003); the Center's lawsuit to compel EPA to consult on pesticides affecting the endangered Barton Springs salamander, see Center for Biological Diversity v. Leavitt, No. 1:04-cv-00126-CKK (D.D.C. filed Jan. 2004); and Californians for Alternatives to Toxics v. EPA, No. C00-3150 CW (N.D. Cal. Sept. 18, 2002), which resulted in a consent decree establishing a schedule for EPA to consult on certain forest use pesticides that affect listed plants and salmonids.

IV. THE COUNTERPART REGULATIONS

50. Expressing alarm at the Washington Toxics Coalition litigation, and raising the specter of more such litigation, the chemical industry and agricultural interests mounted an intensive lobbying effort to convince EPA to devise a regulatory mechanism for limiting the range of pesticides that would be subject to full formal consultation. They proposed a self-

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consultation scheme in which EPA would be able to make "not likely to adversely affect" determinations without obtaining the Services' concurrence and supported using EPA risk assessments for Section 7 consultations on pesticide registrations. In lobbying for a regulatory fix, the industry painted a picture of devastating consequences in which pesticides would become unavailable, impacting trade, taking land out of agricultural production, driving small growers out of business, allowing invasive pests to spread, and spreading disease from mosquitoes. These lobbying efforts extended to high-level political appointees at the Council on Environmental Quality, EPA, the Department of Interior, and the Department of Commerce.

1. Advance Notice of Proposed Rulemaking

51. In January 2003, EPA, the Department of Interior, and the Department of Commerce published an advance notice of proposed rulemaking ("ANPR") on ways to streamline and make EPA risk assessments the basis for ESA consultations on pesticide registrations to make the consultations more effective and efficient. 68 Fed. Reg. 3786 (Jan. 24, 2003). The ANPR indicates that EPA and the Services would work to design a program for ESA compliance that minimizes the impacts to agricultural and commodity production. Id. The ANPR envisions a rulemaking that would promulgate counterpart regulations, authorized under the joint consultation regulations to establish alternative consultation procedures. Id.; see 50 C.F.R. § 402.04.

52. The ANPR sought comment on various ways to streamline the process. Most prominently, the Services sought comment on allowing EPA to engage in self-consultation with respect to pesticides that EPA determines are "not likely to adversely affect" threatened or endangered species. Under such a self-consultation scheme, EPA would make "not likely to adversely affect" determinations unilaterally without the Services' review or concurrence. No informal or formal consultation would take place on such pesticides, eliminating the Services'

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oversight in the case-by-case determinations. 68 Fed. Reg. at 3792-93. The ANPR suggests other mechanisms for making consultations more efficient, such as engaging in programmatic consultations on pesticides that share common elements or on various aspects of EPA's risk assessment process. Id. at 3792. The ANPR discusses embarking on a process to revise EPA's risk assessments and then establishing a rebuttable presumption that EPA's effects determinations are adequate or requiring the Services to defer to and rely on EPA's risk assessments for ESA consultation purposes. Id. at 3793. The ANPR sought comment on other issues, such as the meaning of the best science, how to address cumulative effects, and procedures for emergency situations. Id. at 3794.

53. The purported rationale for the suggested changes is that EPA has expertise in ecological risk assessment and resources in the form of staff, data, and models to conduct risk assessments. Id. at 3791. Since EPA already assesses the impacts of pesticides on species as part of the FIFRA process using its expertise and resources, the ANPR seeks ways to avoid having the Services revisit or second-guess EPA's assessments.

2. The Services' Evaluation of EPA's Risk Assessment Process

54. As part of the rulemaking, the Services evaluated EPA's ecological risk assessment process. This evaluation grew out of the FWS's and NMFS's longstanding concerns about the adequacy of EPA's risk assessments.

55. In an earlier review, FWS identified four overriding weaknesses in EPA's pesticide registration analysis procedures. See Summary of EPA's National Pesticide Registration Program (May 14, 2002). First, FWS faulted EPA for basing its risk assessments on lethal effects, while paying insufficient attention to important sublethal effects that occur at a fraction of the lethal dose:

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> EPA's pesticide registration process focuses primarily on lethal effects, failing to adequately account for nonlethal effects that may result. Because of this narrow focus, the abilities of individual pesticides to elicit a wide range of important sub-lethal effects often is not known. For example, EPA may only use data that determine when 50% of the test population dies from exposure to a pollutant within a specified period of time. Sub-lethal or chronic effects, include disruptions or alternations to growth, reproduction, foraging, predator avoidance, etc., that do not directly result in death of the individual; however, such effects may ultimately lead to the death or "take" of the individuals. For example, exposure to specific pesticides appears to dull the senses of San Joaquin kit foxes making them "sluggish" and susceptible to vehicular strikes; or, the presence of diazinon in the water column appears to affect the olfactory ability of certain salmonids, limiting their ability to find their natal streams for spawning, thus potentially eliminating all spawning for these species. In each of these examples EPA determined that their registration actions would either not affect or would not likely adversely affect them.

Id. at 1.

56. Second, EPA requires testing of only a few select animals and therefore lacks relevant data on the impacts of pesticides on reptiles, amphibians, and mussels for which it has no standard testing protocols or appropriate surrogates. Accordingly, "[t]he existing suite of tests have proven to provide little information of value in predicting potential effects to the many species listed under the ESA." Id. at 2.

57. Third, "EPA's pesticide registration process only analyzes the effects of the active ingredient subject to the registration action, while the effects of so called 'inert' ingredients, carriers, or surfactants are sometimes greater." Id.

58. Fourth, "EPA's pesticide registration process does not examine synergistic, additive, or antagonistic effects of pesticide mixtures" or degradates or metobolites. Id. "Without information regarding which registered pesticides are being applied or mixed together along with evaluations of the fate, transport, and effects associated with metabolites and degradants, it appears unlikely that EPA will have sufficient information to assess the potential effects of pesticide registration and use on listed species." Id. FWS noted that: "While EPA

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attempts to address a few of the above deficiencies in their registration process through the use of 'safety factors,' a preliminary review of their application of this process indicates that it is inadequate to accurately assess effects to listed species." Id.

59. Apart from the Services' evaluation of EPA's risk assessment process, FWS has been critical of EPA risk assessments in its comments on particular EPA pesticide risk assessments, such as atrazine and diazinon, and NMFS has raised concerns in its biological opinions on use of certain pesticides in noxious weed spraying programs on public lands. In these assessments, FWS and NMFS have reiterated the concerns spelled out above. See, e.g., FWS Comments on Atrazine (June 27, 2002); FWS Comments on Diazinon (July 20, 2000); ESA § 7 Consultation Biological Opinion re: Travis Tyrrell Seed Orchard at 11, 14 (Dec. 18, 2002); ESA § 7 Consultation Biological Opinion re: Effects of Herbicide Treatment of Noxious Weeds on Lands Administered by the Salmon-Challis National Forest at 30, 33, 34-35 (Sept. 16, 2002).

60. In addition, in NMFS's draft nonconcurrence in EPA's recent effects determinations made for listed salmon as required by Washington Toxics Coalition, NMFS criticized EPA for relying on industry-submitted data and scientific modeling to the exclusion of the peer-reviewed scientific literature and surface water monitoring, for lacking information about residential uses and cumulative exposures, and for lacking critical information about the location and needs of listed species. NMFS Draft Nonconcurrence Letter at 2-3.

61. In January 2004, EPA released a document entitled, Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, describing how it planned to adapt its risk assessment process to address the concerns raised by the Services. The Overview is not intended to be legally binding; EPA may adopt a different approach or consider other types of

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information as long as it provides a detailed explanation for its approach. 69 Fed. Reg. 4465, 4468 (Jan. 30, 2004). The Services then evaluated the Overview against the backdrop of their past critiques of EPA's risk assessments. The Services released a letter describing the results of that evaluation. Letter from William Hogarth, NOAA Fisheries, and Steve Williams, FWS, to Susan Hazen, OPP (Jan. 26, 2004) ("Overview Letter").

62. While the Services reviewed the deficiencies that they had previously identified in EPA's risk assessments, they deviated from their past critiques in significant respects. First, in response to the criticism that EPA lacked the best scientific information, EPA agreed to search the scientific literature and biological, ecological, and critical habitat information for relevant material, although the Overview does not describe how such information will be addressed or incorporated into EPA's effects determinations. Id. at 10-13.

63. Second, given that EPA lacks tests on surrogate amphibian, reptile, and freshwater mussel species, the Services believe that the species data EPA possesses may be of limited inferential value given the unknown range of toxicological sensitivities of the untested species. However, EPA "will discuss species extrapolation uncertainties to ensure that scientific judgments using this data are made in a transparent manner," use such data "to the extent it is deemed sufficiently reliable," and the Services and EPA will work to develop methods to increase confidence in the surrogate species data, such as using new safety factors or testing additional species. Id. at 13-14.

64. Third, EPA has proposed and the Services will allow EPA to make "not likely to adversely affect" determinations based solely on the effects of each pesticide registration in isolation. EPA will not consider cumulative effects or the environmental baseline incorporating other actions impacting the species in making "not likely to adversely affect" or "likely to

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adversely affect" determinations. It will consider such cumulative effects and the environmental baseline only in formal consultations on those pesticide uses that it has determined are "likely to adversely affect" the listed species or its critical habitat. Id. at 21-22.

65. Fourth, the Services had previously taken the position that an effects determination and ESA consultation had to assess all the effects from the pesticide use. The Services had identified significant gaps in data and analysis of critical effects in EPA's risk assessments. In their Overview Letter, however, the Services acceded to EPA's risk assessment process as a quantitative analysis of risk that disregards or sidelines information that cannot be quantified using existing risk assessment methods. In its risk assessments, EPA regularly will decide whether available data provide a basis from which to quantify risk. If not, EPA will identify the data and explain why the data are not used. See id. at 16.

66. For example, while the Services had previously identified a need to assess sublethal effects, cumulative exposures, and species-relevant data, they ultimately accepted transparency in the form of EPA's promise to explain data gaps, uncertainties, and its disregard of data. For sublethal effects, the Services will not require EPA to expand its assessment of such effects beyond the tests it currently requires, despite its past criticisms. Instead, EPA has the option of including sublethal effects data in its risk assessment "if sufficient and reliable information establish a scientifically sound relationship between the proposed sublethal effect and the survival or reproductive capacity of an organism." Id. at 19.

67. Similarly, because EPA currently lacks models to incorporate into its risk assessments available data on the combined effects of toxicologically similar pesticides and the effects of pesticide mixtures, EPA will search the scientific literature, mention available data, and "consider such information as appropriate." Id. at 14, 19. The Services recognize that

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EPA's examination of formulated products "is less robust" than its assessment of pesticide active ingredients and note that the European Union requires and assesses species toxicity data for formulations, as well as active ingredients. Id. at 18. The Services nonetheless accept EPA's commitment to do no more than consider data that are currently accessible without any commitment to require more data in the future. Id.

68. As a related matter, EPA recognizes that its exposure models under-estimate exposure under certain scenarios, even though it calls its exposure models "worst case scenarios." While EPA is developing new models to address some scenarios, it will use the existing models until such time as the new models have received a favorable peer review by EPA's Scientific Advisory Panel. Id. at 15-16.

69. In addition, EPA will generally not use monitoring data unless the data can be quantified and injected into a risk assessment. Otherwise, EPA simply will highlight uncertainties that monitoring data may raise with respect to the numbers used in the risk assessment. Id. at 16.

70. In their evaluation of the Overview, the Services acceded to EPA's risk assessment process, even though it is less protective in fundamental ways than the Services' current approach to Section 7 consultations. The Services acknowledge that when they conduct Section 7 consultations in the absence of complete information, they identify data gaps and give the benefit of the doubt to the species with respect to the data gaps. Id. at 24. In contrast, to address such data gaps, EPA will "incorporate discussion of these uncertainties in the documentation of its assessment. . . and will demonstrate the application of professional scientific judgment in the resolution of the uncertainties." Id. EPA will resolve many of the decisions over the utility of the scientific literature, biological information, or available data on a

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case-by-case basis in its risk assessments. For many such decisions, EPA will "exercise its professional judgment." Id. at 20.

71. The Services conclude that EPA's risk assessment approach as described in the Overview document will reliably assess the effects of pesticides on threatened and endangered species, will appropriately identify actions that are "not likely to adversely affect" listed species or critical habitat, produce effects determinations that are consistent with those that otherwise would be made by the Services, and will produce all information necessary to initiate formal consultation. Id. at 1.

3. Proposed Rule

72. In January 2004, the Services proposed counterpart regulations that provide optional, alternative approaches to consultation that rely on EPA's risk assessments. 69 Fed. Reg. 4465 (Jan. 30, 2004). The proposed rule cites to the joint consultation regulations for authority to issue counterpart regulations to "fine tune" the consultation framework to reflect particular program responsibilities. Id. at 4467; see 50 C.F.R. § 402.04; 51 Fed. Reg. 19,937 (June 3, 1986). However, "such counterpart regulations must retain the overall degree of protection afforded listed species required by the [ESA] and these regulations. Changes in the general consultation process must be designed to enhance its efficiency without elimination of ultimate Federal agency responsibility for compliance with section 7." Id. (preamble to joint consultation regulations).

73. The proposed rule would establish alternative approaches to streamline consultation that could be used at EPA's option. These alternatives address informal consultation, formal consultation, and specific types of FIFRA registrations.

i. Eliminating informal consultation

74. The proposed rule would authorize EPA to make "not likely to adversely affect"

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determinations without the Services' concurrence, if EPA and the Services have entered into an Alternative Consultation Agreement ("ACA") describing how the Services have ensured that EPA will make effects determinations that are consistent with the ESA, the training required for EPA personnel to make effects determinations, how new information and scientific advances will be incorporated into EPA's effects determinations, and recordkeeping and oversight measures to evaluate compliance with the ACA and the ESA. Id. at 4471-72, 4478-79. The Services note that the ACA is not part of the proposed rule, although a draft was made publicly available for comment. Id. at 4472. The proposed rule clarified that the ACA will establish procedures, but no standards for effects determinations, and will impose no limits on EPA's discretion in developing and applying scientific methods. Id. Nor will it create any substantive or procedural rights enforceable by third parties. Instead, it will establish "a flexible, adaptable scheme that will continually evolve and improve over time" and that allows EPA and the Services to depart from the ACA in any particular case by mutual agreement. Id.

75. The draft ACA made available along with the proposed rule is consistent with this description. It would allow EPA staff who have completed "appropriate ESA Section 7 training" to make "not likely to adversely affect" determinations on pesticide registrations without any concurrence by the Services. Draft ACA at 3. Under the draft ACA, EPA would agree to review any new information and any changes to its risk assessments recommended by the Services. Id. at 4-5. EPA could make changes to its risk assessments by providing written notice to the Services. Id. at 5. The Services and EPA would conduct a joint, inter-agency review of a sampling of effects determination to assess how EPA has applied appropriate ESA standards. Id. at 6. The ACA would establish a dispute resolution process in which a panel consisting of personnel from the participating agencies would try to facilitate reaching a consensus on any

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issues that arise. Id. at 7. The Services and EPA could revise the ACA by mutual agreement without conducting notice and comment rulemaking. Id. The ACA could be terminated by mutual agreement, and a party could, after submitting the matter to dispute resolution, unilaterally terminate the ACA as to that party upon a reasonable belief that it has not or likely will not produce reliable or appropriate effects determinations or satisfy ESA or FIFRA requirements. Id. at 8-9. Termination or suspension of the ACA by any party would not create a need to consult informally or obtain a Service's concurrence in any "not likely to adversely affect" determination made prior to the termination or suspension. Id. at 9.

ii. Formal consultation alternatives

76. The proposed rule would allow EPA to pursue alternative formal consultation intended to have EPA's effects determinations become the Services' biological opinions. EPA could either (1) ask the Services to appoint a Service representative to participate in EPA's process of making the effects determination; or (2) submit an effects determination that includes a jeopardy finding and incidental take statement for potential adoption by the Services. 69 Fed. Reg. at 4478-79.

77. If EPA has utilized the option of having a Service representative participate in EPA's process of drafting the effects determination, the Services' ability to seek additional information from EPA after submission of EPA's effects determination for formal consultation is limited in some circumstances, even if EPA has not included the Service representative in all discussions or provided the representative access to all documentation. Id. at 4478-79.

78. Alternatively, if EPA submits a draft jeopardy finding and incidental take statement, the proposed regulations establish procedures that make it relatively simple for the Services to adopt that effects determination as their biological opinion and take statement, while erecting additional procedural hurdles if the Services decide to deviate from the EPA draft. Id. at

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4479. Upon receiving a draft jeopardy finding and take statement, the Services could: (1) issue a written statement adopting the effects determination as is; (2) provide EPA a draft written statement modifying the effects determination and providing a detailed explanation of the data and rationale for any modification; or (3) provide EPA a draft biological opinion making a jeopardy determination and proposing reasonable and prudent alternatives. Id. If a Service decides to deviate from EPA's effects determination, EPA must share the Service's draft modified effects determination or jeopardy biological opinion with the registrant, on request, and must meet with EPA and the registrant at either's request to discuss the Service's review and basis for its findings. EPA and the registrant may submit written comments to the Service. Id.

79. The Services could modify or reject EPA's effects determination only through designated high-level officials in Washington D.C., without any delegation to the regional offices or others who have typically issued biological opinions and concurrences in the past and who would continue to have the authority to adopt EPA's effects determinations without modification. Id.

iii. Expanding the actions subject to truncated emergency consultation procedures

80. The proposed rule would allow EPA to utilize the consultation process set out in the joint consultation regulations for FIFRA Section 18 exemptions. Id. at 4477 (proposed 50 C.F.R. § 402.42(a)(6)). The joint consultation regulations allow informal consultations "[w]here emergency circumstances mandate the need to consult in an expedited manner" for emergency situations "involving acts of God, disasters, casualties, national defense or security emergencies, etc." 50 C.F.R. § 402.05(a). Any required formal consultation must be initiated as soon as practicable after the emergency is brought into control. Id. § 402.05(b).

81. The proposed rule acknowledges that the Services' 1998 Joint Consultation

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Handbook states that FIFRA emergency exemptions would not qualify as emergencies "unless there is a significant unexpected human health risk." 69 Fed. Reg. at 4474-75. However, the proposed rule concludes that emergency consultation procedures should not be limited to FIFRA exemptions where an unexpected human health risk is present. Id.

82. The proposed rule would allow EPA to invoke this authority for exemptions from the FIFRA registration requirements granted under 7 U.S.C. § 136p for particular pesticide uses. While such exemptions may be granted when emergency conditions exist, id., the FIFRA implementing regulations define "emergency conditions" far more broadly than the ESA joint consultation regulations. While some categories for such FIFRA exemptions involve public health emergencies, some are based solely on economic loss. 40 C.F.R. § 166.2 (identifying four exemption categories, one of which can be based on significant economic loss without any adverse health impact); id. 166.3(d) (defining emergency condition to include a situation that will cause significant economic loss). Such emergency exemptions can be granted for three successive years or more while registration of the pesticide is being pursued. Id. § 166.25(b)(2).

83. The proposed rule provides no explanation for why a broader reading of "emergency conditions" that encompasses economic losses is warranted. It contains no discussion of past consultations on emergency exemptions, even though such consultations have occurred. Nor does it describe the types of pest control situations that arise under FIFRA's exemption provision.

iv. Rationale

84. As with the ANPR, the proposed rule explains that it is designed to take advantage of EPA's expertise and resources in risk assessment and to streamline consultation in anticipation of a large number of pesticide consultations in the coming years due to the backlog, litigation compelling EPA to consult, and imminent re-registration decisions. 69 Fed. Reg. at

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4470-71. "The Services believe that EPA's expertise in ecological risk assessment of pesticides, together with the safeguards built into the alternative consultation agreement, make case-by-case discussions and written concurrences in EPA's NLAA determinations unnecessary for FIFRA actions." Id. at 4472. The proposed rule indicated that EPA and the Services are committed to implementing the rule "in a manner that will be equally as protective of listed species and designated critical habitat as the current procedures that require written concurrence from the Service." Id. The Services also stated that the proposed rule would improve species protection by reducing the Services' workload and allowing it to focus on consulting and establishing mitigation for pesticides that pose greater risks to listed species. Id. at 4471.

85. Throughout the proposed rule, the Services relied on their evaluation and endorsement of EPA's risk assessment process as described in the Overview document. The Services reiterated the conclusions made in that evaluation, even as they acknowledged that the Overview document is not legally binding and that EPA can deviate from it as long as it explains its basis for using other data, factors, or methods. The Services signed off on EPA's risk assessment process through the evaluation of the Overview document, without engaging in any Section 7 consultation that would assess the risk assessment process in accordance with the ESA's best science and other standards.

4. NEPA Compliance

86. In the proposed rule, the Services recognized that the counterpart regulations constitute a major federal action subject to NEPA. On July 2, 2004, the Services released an environmental assessment ("EA") on the counterpart regulations for public comment. 69 Fed. Reg. 40,346 (July 2, 2004). The EA analyzed two alternatives: the proposed action and no action. The proposed action coincides with the proposed rule, while the no action alternative envisions consultation proceeding in accordance with the existing joint consultation regulations

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but with EPA abiding by the Overview document.

87. The Services eliminated from consideration the other options that it suggested in the ANPR, such as programmatic consultations on nearly identical pesticides or pesticides that share common exposure or toxicological profiles or on standardized aspects of EPA's risk assessments or mitigation strategies. EA at 19-20. Because this and the focused consultation approach identified in the ANPR would require involvement of the Services in concurrence decisions, the Services decided that these alternatives would not address the need to improve consultation efficiency by eliminating such written concurrences. Id. at 20-21. The Services had previously identified the purpose and need for the counterpart regulations as increasing efficiency of the consultation process, but not specifically as eliminating the need for the Services' concurrence in "not likely to adversely affect" determinations. 69 Fed. Reg. at 4470-71. The EA narrows the purpose and need so that the self-consultation is the only viable alternative.

88. The EA's analysis of the proposed rules' effects spans less than eight pages. The EA characterizes the proposed rule as a procedural change that leaves EPA's substantive duties to avoid jeopardy and adverse modification intact. EA at 22. Because the standards for making effects determinations remain those set out in the ESA, the joint consultation regulations, and the consultation handbook, the EA concludes that "EPA will reach the same NLAA determinations that the Services would reach; therefore exactly the same outcomes would be expected under the counterpart rule as under the current section 7 process. Therefore, implementing the proposed counterpart rule will not have any adverse biological effects." Id. at 23. The EA supports this conclusion by stating that if EPA adheres to the Overview document, it will use the best science and "correctly make" effects determinations. Id. The EA reiterates the rationale provided in the

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proposed rule stating that the rule will accelerate consultations, making resources available to register less toxic pesticides more quickly and to consult and implement mitigation for pesticides that require formal consultation. In contrast, the EA concludes that the no action alternative would result in duplicative analysis and delay and would make EPA vulnerable to ESA citizen suits that might compel consultations on pesticide registrations and result in injunctions restricting pesticide use during consultation. Id. at 27.

89. The EA refuses to assess the impacts of FIFRA actions that might occur under the proposed rule. It indicates that such impacts result from the actions taken during the implementation of FIFRA, rather than the procedural changes in the consultation process. The effects of FIFRA actions are not considered because "this regulations does not change the effects analysis, or EPA's obligations to ensure the FIFRA actions are not likely to" cause jeopardy or adverse modification. Id. at 28.

90. The EA never discusses how EPA addresses data gaps, uncertainties in its risk assessments, the lack of available data on critical impacts, the biological needs of listed species, or the fact that the Overview document describes a newly modified approach that has never been implemented fully by EPA. Nor does the EA analyze the impacts of components of the proposed rule other than the self-consultation proposal. For example, it never assesses the impacts of allowing economically based emergency situations to sidestep the ordinary consultation process. Nor does it assess the extent to which the Services will obtain the best available science through the alternative formal consultation processes or whether those processes may increase pressure to issue no-jeopardy biological opinions.

91. The public comment period closed on Friday, July 23, 2004. Just four days later, on July 27, 2004, the Departments of Interior and Commerce adopted the counterpart

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regulations. The adoption of the regulations took place before the Services analyzed or responded to the public comments on the EA. Nonetheless, in the final rule, the Services conclude based on the EA that "the action does not have any significant effects" and that a finding of no significant impact has been prepared. 69 Fed. Reg. 47.732, 47,759 (Aug. 5, 2004).

5. Final rule

92. The Departments of Interior and Commerce signed the counterpart regulations on July 27, 2004, and the regulations were published in the Federal Register on August 5, 2004, with an effective date of September 7, 2004. 69 Fed. Reg. 47,732 (Aug. 5, 2004). The final rule adopts the proposed rule with only minor word changes. Id. at 47,758. It also reiterates the proposed rule's rationale for each aspect of the counterpart regulations.

93. The Services received more than 125,000 public comments with the comments opposing the counterpart regulations by a 2 to 1 margin. Id. at 47,740. In responding to public comments that criticized EPA's risk assessments, the Services place great faith in EPA's promised, yet-untested improvements set out in the Overview document, and EPA's commitment to use its best professional judgment on a case-by-case basis and to document how it addresses data gaps, scientific evidence that cannot be translated into quantified risk assessments, and uncertainties. See, e.g. id. at 47,747-52. Where credible scientific evidence reveals impacts, but EPA lacks a scientific model to quantify those impacts for use in a risk assessment, the Services conclude that EPA's approach uses the best science even if it discounts those impacts. E.g., id. at 47,750-51.

94. The Services also state generally that EPA uses conservative assumptions in its risk assessments, even though it concedes in many particular areas the risk assumptions are not conservative but rather overlook and minimize what could be significant impacts. Id. at 47,747-50.

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95. The Services' response to comments clarifies that EPA will evaluate cumulative effects and the environmental baseline only for actions that it deems "likely to adversely affect" listed species or their critical habitat. Id. at 47,749, 47.754. EPA will make "not likely to adversely affect" determinations based solely on the direct and indirect impacts of the particular pesticide registration, and will neither modify the environmental baseline to incorporate such pesticide uses, nor consider the environmental baseline or cumulative effects in making such determinations. Id.

96. On August 26, 2004, EPA and the Services entered into an ACA that is essentially the same as the draft ACA made available for public comment. The Services did not consult on the ACA.

CAUSES OF ACTION

COUNT I

FWS AND NMFS EXCEEDED THEIR AUTHORITY, ACTED ULTRA VIRES, AND ACTED ARBITRARILY, CAPRICIOUSLY, AND CONTRARY TO ESA SECTION 7 BY DELEGATING THEIR ESA CONSULTATIONS TO EPA IN THE COUNTERPART REGULATIONS AND THE ALTERNATIVE CONSULTATION AGREEMENT.

97. Section 7(a)(2) requires that "Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of" critical habitat designated for such species. 16 U.S.C. § 1536(a)(2). Section 7(a)(2) assigns the Secretaries of Interior and Commerce (who have delegated their authority to the Services) the role of consulting with federal action agencies to determine whether their actions are likely to cause jeopardy or adverse modification. This duty is the province of the Services, not action agencies like EPA with respect to pesticide registrations.

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98. The counterpart regulations and ACA delegate the Services' statutory consultation role to EPA. Pursuant to this delegation, EPA will no longer consult with the Services or the Departments of Interior or Commerce on whole categories of pesticide registrations that may adversely affect listed species or their critical habitat. Instead, it will unilaterally determine whether pesticide registrations are likely to jeopardize listed species' survival and/or whether and the extent to which to mitigate harm to individual members of listed species.

99. The counterpart regulations and ACA eliminate the checks and balances provided by ESA Section 7(a)(2) consultation. Under Section 7(a)(2), the Services provide an essential check on the inclination of action agencies to pursue their primary missions despite the consequences for endangered species. The counterpart regulations would eliminate this independent check by allowing EPA to satisfy ESA Section 7(a)(2) through its risk assessments generated to make FIFRA registration determinations, even though EPA makes registration determinations under FIFRA's weaker statutory and scientific standards.

100. EPA self-consultation will eliminate the contribution of the expert wildlife agencies' expertise into ESA compliance. The Services are the repository of a unique body of expertise about threatened and endangered species. First, as part of the listing process, these agencies assess the status of species, including their population viability, trends, and threats to their survival and recovery. Second, in designating critical habitat for listed species, the Services determine which habitat has the biological and physical features essential to the species' recovery. Both in listing species and designating critical habitat, the Services must obtain and use the best available scientific information. Third, the Services are charged with developing recovery plans for listed species. Fourth, the Services conduct assessments of the whole array of

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actions that can adversely affect listed species through both Section 7 consultations and the issuance of incidental take permits for habitat conservation plans under Section 10. Through these assessments, the Services acquire extensive and unrivaled knowledge about the various activities that threaten listed species' survival, mitigation strategies to lessen those threats, the cumulative effects of ongoing and future actions, and the environmental baseline at any given point of time from all of these activities taken together.

101. By promulgating the counterpart regulations and entering into the ACA which authorize EPA to conduct informal consultations without any review or concurrence by the Services, the Services have exceeded their authority, acted ultra vires, and acted arbitrarily, capriciously, and contrary to ESA Section 7(a)(2), in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2).

COUNT II

FWS AND NMFS ACTED ARBITRARILY, CAPRICIOUSLY, AND CONTRARY TO THE ESA BY PROMULGATING COUNTERPART REGULATIONS AND ENTERING INTO THE ACA WHICH FAIL TO ENSURE THAT EPA PESTICIDE REGISTRATIONS ARE NOT LIKELY TO JEOPARDIZE LISTED SPECIES OR DESTROY OR ADVERSELY MODIFY THEIR CRITICAL HABITAT.

102. Section 7(a)(2) imposes an affirmative duty on federal agencies to "insure" that agency actions are not likely to cause jeopardy to the continued existence of listed species or destruction or adverse modification of designated critical habitat. 16 U.S.C. § 1536(a)(2).

103. By using the word "insure," Congress evinced its intent to require the agencies to take affirmative steps to guard against the prohibited jeopardy to listed species or adverse modification of their critical habitat. The definition of "insure" requires far more than mere consideration of a factor. Its plain dictionary definition means "to make certain esp[ecially] by taking necessary measures and precautions." WEBSTER'S NEW COLLEGIATE DICTIONARY 600 (1977); see also BLACK'S LAW DICTIONARY 946 (4th ed. 1951) (defining "insure" as "[t]o make

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sure or secure, to guarantee, as, to insure safety to any one."). In order to "insure" against a likelihood of jeopardy, any risk "must be borne by the project, not by the endangered species." See Sierra Club v. Marsh, 816 F.2d 1376, 1386 (9th Cir. 1987).

104. The counterpart regulations and ACA depart from the "insure" mandate in at least three respects. First, the counterpart regulations and ACA lower the threshold for consultations from "may affect" to "likely to adversely affect" the listed species. In promulgating the joint consultation regulations, FWS and NMFS recognized that allowing an action agency to determine whether a listed species will not likely be adversely affected is "too close to the 'jeopardy' standard of section 7(a)(2)" to go forward without Section 7(a)(2) consultation. See 51 Fed. Reg. 19,926, 19,950 (June 3, 1986). Moreover, while the joint consultation regulations authorize counterpart regulations that modify the consultation processes for particular types of actions, the preamble to 50 C.F.R. § 402.04 clearly envisions that in any such counterpart regulations "the general consultation process is used as a starting point . . .." 51 Fed. Reg. at 19,937. The counterpart regulations and ACA discard the general consultation process for actions that EPA deems "not likely to adversely affect" listed species or their habitat and shift the threshold for consultation from "may affect" to "not likely to adversely affect," which comes perilously close to Section 7's "not likely to jeopardize" standard.

105. Second, the joint consultation regulations' authorization for counterpart rules that supersede the established consultation procedures, see 50 C.F.R. § 402.04, is qualified by the requirement that: "Such counterpart regulations must retain the overall degree of protection afforded listed species required by the Act and these regulations." 51 Fed. Reg. at 19,926. The counterpart regulations and ACA substitute one process – unilateral EPA effects determinations – for another – informal consultation that requires the Services' concurrence in EPA "not likely

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to adversely affect" concurrences. By eliminating the informal consultation process, the counterpart regulations and ACA deprive the Services of any leverage over the underlying actions. In practice, the need for the Services' concurrence has often led the action agencies to modify actions to eliminate or mitigate for harmful effects. In the absence of the need to obtain the Services' approval, EPA will no longer learn of the Services' concerns about particular pesticide uses, nor will it have any incentives to make such changes. Given that the ESA institutionalizes caution through the Section 7(a)(2) consultation process, jettisoning inter-agency consultation for actions that EPA deems "not likely to adversely affect" listed species or their habitat fails to "retain the overall degree of protection afforded listed species" by the ESA and the joint consultation regulations.

106. Third, the delegation of authority to EPA in the counterpart regulations and ACA is far too broad and open-ended to retain the same level of protection afforded by the current informal consultation scheme in which the Services must concur in an action agency's "not likely to adversely affect" determination. Neither the counterpart regulations nor the ACA contains standards that constrain EPA's discretion or otherwise ensure that EPA will make credible and appropriate effects determinations based on the best available science.

107. The Services rely on their evaluation of EPA's risk assessment process and EPA's recent promises toward improvement made to convince the Services to give EPA self-consultation authority. The Services' evaluation defers to EPA's FIFRA risk assessment process, even though EPA retains significant discretion to make case-by-case decisions in applying this process and in addressing credible scientific information that does not fit neatly into its risk assessment models.

108. In the recent past, FWS and NMFS have been extremely critical of EPA's risk

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assessments for failing to account for the full impacts of pesticides on imperiled species. While the Services have backtracked from those critiques and now appear willing to trust EPA to use its best professional judgment to improve its risk assessments, the counterpart regulations and ACA prescribe no sidebars to guarantee that EPA will employ the best science in exercising this professional judgment and in addressing data gaps and uncertainty.

109. The only safeguard in this self-consultation process will come in the form of periodic, after-the-fact reviews conducted jointly by EPA and the Services. If the Services find that EPA has failed to produce reliable or appropriate effects determinations or has failed to satisfy ESA or FIFRA requirements, and the matter is not resolved through the ACA's dispute resolution process, the Services may terminate or suspend the ACA. However, "[t]ermination, suspension, or modification of an alternative consultation agreement does not affect the validity of any NLAA determination made previously under the authority of" the counterpart regulations. 50 C.F.R. § 402.45(c). Even blatantly erroneous NLAA determinations would remain effective.

110. By granting a wholesale delegation of consultation authority, the Services have relinquished ongoing oversight of EPA's effects determinations and compliance with Section 7(a)(2). Such an open-ended delegation provides far less protection than the Services' scrutiny of the propensity of particular pesticides to interact with and harm various types of species based on their toxicity and uses. It eliminates the consultation check on EPA's inclination to approve pesticide uses based on FIFRA risk assessments with little regard for scientific evidence that does not fit neatly into a quantified risk assessment or for the on-the-ground impacts of the pesticides on imperiled species in various regions of the country. This self-consultation scheme contravenes Section 7(a)(2)'s mandate to "insure" that agency actions are not likely to jeopardize listed species or adversely modify their critical habitat.

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111. By promulgating the counterpart regulations and entering into an ACA without sufficient standards or safeguards to ensure that EPA's pesticide registrations are not likely to cause jeopardy or adverse modification, the Services have acted arbitrarily, capriciously, and contrary to ESA Section 7(a)(2) and 50 C.F.R. § 402.04, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2).

COUNT III

FWS AND NMFS ACTED ARBITRARILY, CAPRICIOUSLY AND CONTRARY TO SECTION 7(A)(2) BY FAILING TO RECONCILE THE COUNTERPART REGULATIONS AND THE ACA WITH THE BEST AVAILABLE SCIENTIFIC INFORMATION AND BY FAILING TO ENSURE THAT EPA SELF-CONSULTATIONS WILL USE THE BEST AVAILABLE SCIENCE.

112. Section 7(a)(2) requires the action and expert agencies to use the best science in discharging their Section 7 duties: "In fulfilling the requirements of this paragraph each agency shall use the best scientific and commercial data available." 16 U.S.C. § 1536(a)(2).

113. EPA lacks the institutional expertise in endangered species that the Services uniquely possess. The expert wildlife agencies are generally the repositories of the best scientific evidence given their role in listing threatened and endangered species, designating critical habitat, conducting Section 7(a)(2) consultations, issuing incidental take permits and statements with necessary mitigation measures, and developing recovery plans. Through their involvement in these aspects of ESA implementation, the Services can identify environmental baseline conditions and can predict the cumulative effects of private and governmental actions across the landscape and from disparate activities. The Services' participation in Section 7(a)(2) consultations injects their unique, comprehensive scientific knowledge into such consultations. EPA self-consultation is no substitute for the review and oversight of the expert agencies that oversee all aspects of the ESA protective scheme.

114. The counterpart regulations and ACA allow EPA to make effects determinations

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based on the risk assessments generated to make FIFRA decisions. However, FIFRA registration and re-registration determinations are made under an unreasonable adverse effects standard that allows EPA to balance the risks to health and the environment, including endangered species, against the economic benefits of the pesticide use. Moreover, EPA generally refrains from taking action to cancel a pesticide registration until it has filled data gaps with industry studies that often take years to complete. In contrast, the ESA makes Section 7(a)(2) consultations subject to the best available science, which requires agencies to act based on the information in hand, rather than wait for the generation of studies conducted to fill data gaps, the development of scientific models to quantify impacts, or peer review of models or studies.

115. Even apart from these institutional constraints, EPA has consistently failed to use the best available science in its FIFRA risk assessments concerning ecological impacts on fish and wildlife. FWS and NMFS have found EPA's ecological risk assessments inadequate to account for pesticides' species impacts because of significant gaps in data on pesticide effects on species and their habitat and EPA's failure to incorporate peer-reviewed scientific literature and surface water monitoring into its risk assessments.

116. In their recent evaluation of EPA's risk assessment process, the Services have reiterated these concerns, and EPA has acknowledged problems with its risk assessment process, but EPA has promised to make some improvements. The hoped-for improvements are not prescribed in binding regulations, nor have they been implemented or tested in practice. Moreover, EPA still lacks adequate information and methods to assess the impacts of urban pesticide use, pesticide effects on amphibians and reptiles, sublethal effects, and cumulative uses and exposures to pesticide active ingredients, inert ingredients, and mixtures.

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117. The Services recognize that EPA has failed to correct many pitfalls in its assessments, yet they are now willing to defer to EPA's use of its "best professional judgment" in deciding how to use peer-reviewed scientific literature, surface water modeling, and evidence of effects that cannot be quantified and incorporated into a quantitative risk assessment. EPA has promised to document how it resolves data gaps and uncertainties, as well as how it decides to use such available data on a case-by-case basis. EPA's "best professional judgment" cannot be equated with the best available science particularly given its poor track record, the importance of the gaps in its assessments, the Services' past critiques, and the lack of meaningful standards constraining how EPA will exercise such discretion.

118. The Services have dispensed with case-by-case review of EPA's "not likely to adversely affect" determinations based on their evaluation of EPA's risk assessment process. However, EPA's risk assessment process can change at EPA's discretion and EPA can deviate from the process described in its Overview document with notice to the Services of any such changes. Accordingly, the Services have given EPA the authority to make unilateral "not likely to adversely affect" determinations and to conduct self-consultations based on a risk assessment process and assurances that may not be implemented in the effects determinations that EPA will actually make.

119. Even if EPA adheres to the risk assessment process described in the Overview document, it will decide how to address data gaps, uncertainties, scientific literature, surface water monitoring, and particular data on a case-by-case basis. The preamble to the final rule recognizes that EPA often lacks necessary data. EPA will then make decisions "on a case-by-case basis, using best professional judgment" and will document how it addressed data gaps and uncertainties. 69 Fed. Reg. at 47,747. It is arbitrary, capricious, and contrary to the Services'

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Section 7(a)(2) duties for the Services to conclude that "case-by-case discussions and written concurrence" by the Services is unnecessary (69 Fed. Reg. at 47,737), when EPA will be making decisions on a case-by-case basis with no clear standards to constrain its discretion or to enable the Services to ascertain in advance how EPA will exercise its discretion.

120. By signing off on a process that requires use of data only when it can be quantified or modeled for incorporation into in a quantitative risk assessment and that leaves use of other data to EPA's discretion, the Services have essentially substituted a best available quantified data standard for the EPA's best available science standard. While EPA has committed to document how it considers such data, such documentation could consist of merely mentioning it without basing the effects determination on any data that cannot be modeled or quantified.

121. By granting EPA self-consultation authority through the counterpart regulations and ACA, the Services have eliminated the ESA-prescribed method for insuring that ESA consultations are based on the best available science. The ESA requires action agencies to provide the best available science to the Services along with their requests for consultation, and the Services themselves must use the best science in developing their concurrences and biological opinions. EPA's promised improvements in its risk assessments have never been subjected to the thorough scrutiny of the ESA Section 7(a)(2) consultation process to ensure that they embody the best available science and the full range of effects that need to be assessed in a consultation.

122. FWS and NMFS have acted arbitrarily, capriciously, and contrary to ESA Section 7(a)(2), in violation of the APA, 5 U.S.C. § 706(2)(A), by failing base the counterpart regulations and ACA on the best available science and by failing to ensure that EPA self-

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consultations will use the best available science.

COUNT IV

THE SERVICES ACTED ARBITRARILY, CAPRICIOUSLY, AND CONTRARY TO ESA SECTION 7(A)(2) IN ISSUING COUNTERPART REGULATIONS AND ENTERING INTO AN ACA THAT AUTHORIZE EPA TO MAKE "NOT LIKELY TO ADVERSELY AFFECT" DETERMINATIONS WITHOUT CONSIDERING THE ENVIRONMENTAL BASELINE OR CUMULATIVE EFFECTS.

123. In order to insure that an action will not jeopardize the continued existence of a listed species or adversely modify designated critical habitat, both the action agency and the Services must assess the full impacts of the action when added to the impacts of other ongoing actions and the current environmental conditions in the impacted area.

124. Under the joint consultation regulations, federal agencies must assess the effects of the action against the backdrop of past and ongoing activities. The joint consultation regulations define "effects of the action" as the direct and indirect effects of the action together with interrelated and interdependent actions "that will be added to the environmental baseline." 50 C.F.R. § 402.02. The environmental baseline includes the past and present impacts of all federal, state, and private actions and other human activities in the action area. While the anticipated impacts of proposed federal actions are added to the baseline only after they have undergone Section 7(a)(2) consultation, this limitation is inapplicable to past and present actions.

125. EPA and the Services must also assess cumulative effects in Section 7(a)(2) consultations on pesticide registrations. Cumulative effects are effects of future state or private activities that are reasonably certain to occur in the action area. 50 C.F.R. § 402.02.

126. In consultations on pesticide registrations, EPA and the Services must assess the impacts of a pesticide registration in conjunction with all other ongoing pesticide use in the action area, as well as current environmental conditions and trends.

127. In the counterpart regulations and ACA, the Services have authorized EPA to

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evaluate cumulative effects and the environmental baseline only for actions that it deems "likely to adversely affect" listed species or their critical habitat. Id. at 47,749, 47.754. EPA will make "not likely to adversely affect" determinations based solely on the direct and indirect impacts of the particular pesticide registration, and will neither modify the environmental baseline to incorporate such pesticide uses, nor consider the environmental baseline or cumulative effects in making such determinations. Id.

128. The Services have acted arbitrarily, capriciously, contrary to Section 7(a)(2), and contrary to the joint consultation regulations, in violation of the APA, 5 U.S.C. § 706(2)(A), by authorizing EPA to make unilateral effects determinations without considering the environmental baseline and/or cumulative effects.

COUNT V

FWS AND NMFS ACTED ARBITRARILY, CAPRICIOUSLY, AND CONTRARY TO THE ESA AND THE JOINT CONSULTATION REGULATIONS BY ESTABLISHING AN OPTIONAL FORMAL CONSULTATION PROCESS BASED ON A RATIONALE THAT RUNS COUNTER TO THE RECORD AND THE BEST SCIENCE.

129. The counterpart regulations allow EPA to pursue what is called "optional formal consultation" in which EPA includes in its effects determinations: (a) a jeopardy conclusion and a description of available reasonable and prudent alternatives in the event of a jeopardy finding; (b) an incidental take statement, including reasonable and prudent measures and terms and conditions to implement those measures; and (c) a summary of any information or recommendations from the registrant. 50 C.F.R. § 402.46. A Service can adopt EPA's effects determination in which case it becomes the Service's biological opinion and incidental take statement. Id. § 402.46(c)(1)(i), (d). The Services may delegate the authority to adopt EPA's effects determinations, however they see fit.

130. The counterpart regulations establish more cumbersome procedures if a Service

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proposes to modify EPA's effects determination or write its own biological opinion making a jeopardy finding. Id. § 402.46(c)(1)(ii) & (iii), (c)(2). The Services must provide EPA a draft of any written statement modifying the effects determination, along with a detailed explanation of the data and rationale for the modification, or a draft biological opinion making a jeopardy determination and proposed reasonable and prudent alternatives. Id. § 402.46(c)(1)(ii) & (iii). The counterpart regulations then allow for review by, meetings with, and comments from EPA and the registrant before the Service may finalize the biological opinion. Id. 402.26(c)(2).

131. The counterpart regulations allow only designated high-level officials to modify EPA effects determinations or sign biological opinions that differ from jeopardy findings submitted by EPA. This authority cannot be delegated to the regional offices or others who typically sign biological opinions. Id. § 402.46(e).

132. Under Section 7(a)(2), the Services "shall provide to the Federal agency and the applicant, if any, a written statement setting forth the Secretary's opinion, and a summary of the information on which the opinion is based, detailing how the agency action affects the species or its critical habitat. 16 U.S.C. § 1536(b)(3)(A). The Services must similarly issue incidental take statements. Id. § 1536(b)(4). This authority cannot be delegated to the action agency. A biological opinion and incidental take statement must embody the independent assessment and conclusions of the Services based on the best available scientific information.

133. The Services' rationale for the optional formal consultation is that EPA has the expertise and resources to conduct ecological risk assessments that can serve as the basis for effects determinations on pesticide registrations, and the Services' review is unnecessary and duplicative. EPA's risk assessment process and methods as described in the Overview document do not constitute the best available scientific information for consultations on pesticide

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registrations. The Services recognize that EPA lacks data and methods to assess many effects of pesticides on listed species and their habitat. The Services will allow EPA to use its best professional judgment to fill those data gaps, to consider scientific information that does not fit within its quantified risk assessment models, and to address uncertainties. Since EPA will make such decisions on a case-by-case basis, the Services' review and independent assessment of the underlying data, issues, and uncertainties is not duplicative. The Services' rationale for the optional formal consultation procedure runs counter to the best science, the record before the agency, and the conclusions reached by the Services both in the rulemaking process and previously in evaluations of EPA ecological risk assessments of pesticides.

134. The Services acted arbitrarily, capriciously, and contrary to the best science and the record, in violation of the APA, 5 U.S.C. § 706(A), by adopting the optional formal consultation process for reasons that run counter to the best science and the evidence before the agency.

COUNT VI

EPA ACTED ARBITARILY, CAPRICIOUSLY, AND CONTRARY TO THE ESA AND THE JOINT CONSULTATION REGULATIONS IN MAKING ALL FIFRA SECTION 18 EXEMPTIONS, EVEN THOSE BASED SOLELY ON ECONOMIC LOSSES, SUBJECT TO TRUNCATED CONSULTATION PROCEDURES ESTABLISHED FOR HUMAN HEALTH EMERGENCIES.

135. The proposed rule would make all FIFRA Section 18 exemptions subject to informal consultation with formal consultation to follow as soon as practicable after the emergency is brought under control. 50 C.F.R. § 402.42(a)(6); see 50 C.F.R. § 402.05.

The joint consultation regulations allow informal consultations "[w]here emergency circumstances mandate the need to consult in an expedited manner" for emergency situations "involving acts of God, disasters, casualties, national defense or security emergencies, etc." 50 C.F.R. § 402.05(a).

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136. The Services' 1998 joint consultation handbook describes the expedited consultations as applying to "an emergency (natural disaster or other calamity)." "Calamity" is defined as "an extraordinarily grave event marked by great loss and lasting distress and affliction." Webster's New Collegiate Dictionary (1977).

137. The descriptions of an emergency in both the joint consultation regulations and the joint consultation handbook refer to situations that involve threats to human life and health. Accordingly, emergencies extent to natural disasters, war, or national security situations.

138. The joint consultation handbook further states (at 8-1) that: "Predictable events, like those covered in Emergency Use Permits issued by the Environmental Protection Agency for pesticide applications, usually do not qualify as emergencies under the section 7 regulations unless there is a significant unexpected human health risk." The emergency use permits referred to in the handbook are those granted under Section 18 of FIFRA.

139. FIFRA regulations define Section 18 "emergency conditions" far more broadly than the ESA joint consultation regulations. While some categories for such exemptions involve public health emergencies, some are based solely on economic loss. 40 C.F.R. § 166.2 (identifying four exemption categories, one of which can be based on significant economic loss without any adverse health impact); id. 166.3(d) (defining emergency condition to include a situation that will cause significant economic loss). Such economic-based Section 18 exemptions can be granted for three successive years or more while registration of the pesticide is being pursued. Id. § 166.25(b)(2).

140. The counterpart regulations allow EPA to invoke emergency expedited consultation procedures for FIFRA Section 18 exemptions even where there is no human health risk. The Services have described no problems that have arisen in past consultations on Section

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18 exemptions or any explanation for why a broader reading of "emergency conditions" that encompasses economic losses is warranted. Nor have they explained why they are now deviating from the position taken in the joint consultation handbook.

141. It is arbitrary, capricious, and contrary to the ESA and the joint consultation regulations and handbook, in violation of the APA, 5 U.S.C. § 706(2)(A), for the Services to make all FIFRA Section 18 exemptions subject to expedited consultation procedures even where no human health risk is presented.

COUNT VII

FWS AND NMFS ACTED ARBITRARILY, CAPRICIOUSLY, AND CONTRARY TO NEPA AND ITS IMPLEMENTING REGULATIONS BY FAILING TO PREPARE AN ENVIRONMENTAL IMPACT STATEMENT ASSESSING ALTERNATIVES TO AND THE FULL IMPACTS OF THE COUNTERPART REGULATIONS AND THE ACA.

142. Under NEPA, all federal agencies must prepare environmental impact statements ("EISs") on "every recommendation and report on proposals for legislation and other major federal actions significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C). The counterpart regulations constitute a major federal action subject to NEPA. See 40 C.F.R. § 1508.18 ("major Federal action" includes agency regulations).

143. The Council on Environmental Quality ("CEQ"), which is charged with issuing binding NEPA implementing regulations, has established a process for determining whether a major federal action has significant environmental effects warranting preparation of an EIS. Under the CEQ regulations, an agency may avoid preparing an EIS if it: (1) prepares an environmental assessment or EA identifying and analyzing the action's environmental effects; and (2) makes a finding of no significant impact, which presents the agency's reasons for concluding that the action's environmental effects are not significant. Id. §§ 1501.4(b), (e); 1508.9; 1508.1.3.

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144. An EA, like an EIS, must assess a reasonable range of alternatives to the proposed action. The EA for the counterpart regulations fails to consider any alternatives to the proposed rule. The only options considered are the proposed rule and the no action alternative. The Services dismissed other alternatives presented in the ANPR, such as programmatic consultations on pesticides with common toxicological effects or exposures or on aspects of EPA's risk assessment process or mitigation strategies. While such consultations would streamline subsequent consultations, the articulated purpose and need for the regulatory changes, they would not eliminate the Services' concurrences in EPA "not likely to adversely affect" determinations. By dismissing other alternatives on this basis, the Services have impermissibly redefined the purpose and need so narrowly that there is only one possible alternative to consider.

145. An EA, like an EIS, must assess the environmental impacts of the proposed action and viable alternatives, including cumulative effects, i.e., those resulting "from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions . . . . Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time." Id. §§ 1508.7-1508.8.

146. The Services decided that the counterpart regulations would have no adverse effect based on its conclusion that EPA would produce effects determinations identical to those that the Services would otherwise make. The premise on which this conclusion is based – that EPA will make equally protective effects determinations – is the question that must be explored in the EA or EIS, not the basis for eliminating the need for such an analysis. Moreover, the Services cannot eliminate any consideration of the ultimate pesticide registration modifications that will or will not result from the consultation process under the counterpart regulations. While

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the counterpart regulations establish the process for making effects determinations, the Section 7(a)(2) consultation process is inextricably intertwined with the substantive duty to avoid jeopardy and adverse modification and to mitigate harm from incidental take.

147. The EA describes the various components of the counterpart regulations but it limits its analysis of environmental impacts to self-consultation. The EA never addresses the impacts of the expedited consultations for FIFRA Section 18 exemptions. Nor does it discuss the impacts of the optional formal consultation process in which EPA submits a draft biological opinion and incidental take statement and the Services must go through numerous procedural steps that create disincentives to any disagreement by the Services with EPA's draft.

148. Under NEPA, an EIS must be prepared if substantial questions are raised as to whether a project may cause significant degradation of the environment. The CEQ regulations list factors that must be considered in determining the significance of an action's environmental effects, including whether the effects or actions are highly controversial, whether the effects are highly uncertain, whether the action establishes a precedent, whether the action contributes to cumulative effects, whether the action may adversely affect threatened or endangered species or their habitat, and whether the action threatens to violate federal environmental law. Id. § 1508.27(b).

149. Authorizing self-consultation is highly controversial, establishes a precedent for the future, and short-circuits the prescribed standards in the ESA. The effects of pesticide uses on listed species and their habitat are pervasive and complex. Signing off on EPA's risk assessment process, which is largely based on promises to improve its past performance and risk assessment methods, is controversial and fraught with uncertainties. The counterpart regulations eliminate consideration of cumulative effects and the environmental baseline in "not likely to

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adversely affect" determinations, ensuring that cumulative impacts will escape FWS's and NMFS's scrutiny. Allowing EPA to draft jeopardy findings and incidental take statements and making them the presumptive biological opinion through the optional formal consultation process would establish a new precedent for conducting Section 7(a)(2) consultations that will lead to increased political pressure to weaken protections for threatened and endangered species.

150. Under the CEQ regulations, the counterpart regulations will have significant environmental impacts that warrant preparation of an EIS, rather than an EA. Indeed, the final rule makes a finding that the counterpart regulations constitute "a significant rule because of the legal or policy issues it has raised" for purposes of Executive Order 12,866 on regulatory planning and review. Accordingly, the Office of Management and Budget conducted a review the regulations. 69 Fed. Reg. at 47,758.

151. By preparing an EA that fails to consider alternatives to the counterpart regulations and that fails to assess the full impacts, including the cumulative impacts, of the consultations and the pesticide registrations that will result from the truncated processes authorized in the counterpart regulations and the ACA, and by failing to prepare an EIS, the Services acted arbitrarily, capriciously, and contrary to NEPA and the CEQ implementing regulations, in violation of the APA, 5 U.S.C. § 706(2)(A).

RELIEF

WHEREFORE, plaintiffs pray that this Court:

(A) Declare that the FWS and NMFS acted arbitrarily, capriciously, and contrary to the ESA and the joint consultation regulations, in violation of the APA, 5 U.S.C. § 706(2)(A), in adopting the counterpart regulations and entering into the ACA.

(B) Enjoin and set aside the counterpart regulations and the ACA;

(C) Declare that FWS and NMFS acted arbitrarily, capriciously and contrary to NEPA

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705 Second Ave., Suite 203
Seattle, WA 98104
(206) 343-7340

and the CEQ regulations, in violation of the APA, 5 U.S.C. § 706(2), by failing to prepare an EIS on the counterpart regulations and the ACA, and by failing to evaluate alternatives to, and the full impacts of, the counterpart regulations and ACA;

(D) Award plaintiffs their costs and attorneys' fees in this action pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412; and

(E) Grant such other and further relief as the Court may deem just and proper.

Respectfully submitted this 23rd day of September, 2004.

/S/_____

PATTI GOLDMAN (WSB #24426)
Earthjustice
705 Second Avenue, Suite 203
Seattle, WA 98104
(206) 343-7340
(206) 343-1526 *[FAX]*
pgoldman@earthjustice.org