ATTACHMENT E

Washington Toxics Coalition v. Dep't of Interior, No. 2:04-cv-01998-JCC (W.D. Wash. Aug. 24, 2006)

The Honorable John C. Coughenour

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

WASHINGTON TOXICS COALITION; NORTHWEST COALITION FOR ALTERNATIVES TO PESTICIDES; NATIONAL WILDLIFE FEDERATION; 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; FISH AND WILDLIFE SERVICE; UNITED STATES DEPARTMENT OF COMMERCE; and NATIONAL MARINE FISHERIES SERVICE;

Defendants,

and

CROPLIFE AMERICA; WASHINGTON FRIENDS OF FARMS AND FORESTS; WASHINGTON STATE POTATO COMMISSION; NATIONAL POTATO COUNCIL; WASHINGTON STATE FARM BUREAU; IDAHO FARM BUREAU; FEDERATION OF WHEAT GROWERS; WASHINGTON GOLF COURSE SUPERINTENDENTS ASSOCIATION; HOP GROWERS OF WASHINGTON; AND WASHINGTON STATE HORTICULTURAL ASSOCIATION;

Defendant-Intervenors.

CASE NO. C04-1998C

ORDER

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I. INTRODUCTION

This matter has come before the Court on the parties' cross-motions for summary judgment. Having carefully considered the papers filed by the parties and the entire record now before the Court, the Court has determined that no oral argument shall be necessary. For the following reasons, the Court hereby GRANTS in part and DENIES in part Plaintiffs' motion, GRANTS in part and DENIES in part the Federal Defendants' motion, and GRANTS in part and DENIES in part the Defendant-Intervenors' motions.

II. BACKGROUND

Plaintiffs, a group of organizations who have an interest in preserving and conserving the environment, brought this suit to challenge certain actions taken by the Fish and Wildlife Service ("FWS") and the National Marine Fisheries Service ("NMFS") (collectively "the Services"), alleging that the actions violate section 7 of the Endangered Species Act ("ESA"), 16 U.S.C. § 1536, and that they were taken without adherence to the procedural requirements of the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4332.

A. Statutory and regulatory context of ESA section 7 consultations

The Endangered Species Act provides certain protections to species listed under ESA section 4 as "endangered" or "threatened" (collectively "listed species"). Section 7(a)(2) of the ESA states:

> 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 habitat of such species which is determined by the Secretary, after consultation as appropriate with affected States, to be critical . . . . 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) (parenthetical omitted). The "Secretary" referred to in the statute, in the case of the Secretary of Commerce (for some marine species), has delegated his ESA role to NMFS, and in the case of the Secretary of the Interior (for the remaining listed species), has delegated her ESA role to FWS.

In 1986, the Services jointly issued regulations further shaping the section 7 consultation process. 51 Fed. Reg. 19,926 (1986). These regulations created three categories of federal agency action possibly requiring consultation: actions likely to adversely affect ("LAA"), actions not likely to adversely affect ("NLAA") and actions that will have no effect on listed species or critical habitat. LAA actions require formal consultation, while NLAA actions may fulfill the statutory and regulatory requirements with a streamlined informal consultation. No consultation is required for actions that have no effect on listed species.

The regulations provided that "[t]he consultation procedures set forth in this Part may be superseded for a particular Federal agency by joint counterpart regulations among that agency, [FWS], and the [NMFS]. 50 C.F.R. § 402.04 (effective June 3, 1986). The regulations require, however, that "[s]uch counterpart regulations must retain the overall degree of protection afforded listed species required by the Act and these regulations." 50 C.F.R. § 402.04; 51 Fed. Reg. at 19,937.

B. Promulgation of the counterpart regulations regarding FIFRA actions

In 2004, pursuant to this authority to devise different consultation procedures, the Services promulgated new counterpart regulations for Environmental Protection Agency ("EPA") actions under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). Joint Counterpart Endangered Species Act Section 7 Consultation Regulations, 69 Fed. Reg. 47,732 (Aug. 5, 2004) (codified at 50 C.F.R. §§ 402.40–.48).

"FIFRA is the primary statute under which EPA regulates the use of pesticides in the United States." 69 Fed. Reg. at 47,733 (citing 7 U.S.C. § 136 *et seq.*). In general, a pesticide may not be sold or distributed unless it has a license, or "registration," from EPA. FIFRA section 12(a)(1). EPA "shall register a pesticide if" among other things, "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(5). Recognizing that environmental standards and data evolve, FIFRA built in a periodic re-registration process, with the goal of achieving a review of each pesticide registration every fifteen years. 7 U.S.C. § 136a(g)(1). Although this re-registration process had been on the books since 1972, "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." (Compl. ¶ 34 (citing GEN. ACCOUNTING OFFICE, EPA'S FORMIDABLE TASK TO ASSESS AND REGULATE THEIR RISKS 3 (1986)).)

C. Effect of counterpart regulations

The parties do not dispute that EPA is faced with a task of gargantuan proportions, nor do they dispute that the counterpart regulations challenged by Plaintiffs are an attempt to streamline and accelerate the process of registration and re-registration. *See, e.g.*, 69 C.F.R. at 47,732 (explaining that "[t]hrough this final joint rulemaking, the FWS and NOAA adopt additional regulations to enhance the efficiency and effectiveness of the consultation process under section 7 of the ESA and to provide alternatives to the way EPA now consults with the Services under the ESA on regulatory actions under FIFRA involving pesticides").

Prior to adoption of the counterpart regulations, an NLAA determination could only be made by an agency with the written concurrence of the Director of the appropriate Service, and after preparation of a biological assessment by the appropriate Service or informal consultation with that Service. 50

C.F.R. § 402.14. The counterpart regulations now permit EPA to make NLAA determinations without informal consultation or the Services' concurrence if EPA and the Services have entered into an "alternative consultation agreement" ("ACA") meeting certain requirements, *see* 50 C.F.R. § 402.45.

In the context of actions requiring formal consultation, the potential streamlining effect of the counterpart regulations is even greater. Where initiation of a written request for consultation used to trigger a whole host of Service responsibilities culminating in the production of a comprehensive biological opinion and discussion of that opinion with the requesting agency and any applicant, *see* 50 C.F.R. § 402.14(g),[1] under the counterpart regulations, the Services' obligations are now limited to (a)

[1] Under the default rules (as opposed to the counterpart rules governing FIFRA actions), the Services were required to:

> (1) Review all relevant information provided by the Federal agency or otherwise available. Such review may include an on-site inspection of the action area with representatives of the Federal agency and the applicant.
>
> (2) Evaluate the current status of the listed species or critical habitat.
>
> (3) Evaluate the effects of the action and cumulative effects on the listed species or critical habitat.
>
> (4) Formulate its biological opinion as to whether the action, taken together with cumulative effects, is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.
>
> (5) Discuss with the Federal agency and any applicant the Service's review and evaluation conducted under paragraphs (g)(1)-(3) of this section, the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant can take to avoid violation of section 7(a)(2). The Service will utilize the expertise of the Federal agency and any applicant in identifying these alternatives. If requested, the Service shall make available to the Federal agency the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The 45-day period in which the biological opinion must be delivered will not be suspended unless the Federal agency secures the written consent of the applicant to an extension to a specific date. The applicant may request a copy of the draft opinion from the Federal agency. All comments on the draft biological opinion must be submitted to the Service through the Federal agency, although the applicant may send a copy of its comments directly to the Service. The Service will not issue its biological opinion prior to the 45-day or extended deadline while the draft is under review by the Federal agency. However, if the Federal agency submits comments to the Service regarding the draft biological opinion

adopting in full EPA's effects determination, (b) adopting EPA's effects determination as modified by the Services, with a detailed explanation of the scientific and commercial data and rationale supporting any modification, or (c) providing EPA with "a draft of a biological finding that the proposed FIFRA action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat, and describing any reasonable and prudent alternatives if available," 50 C.F.R. § 402.46(c). Further streamlining the process is the fact that under the counterpart regulations, Service discussion with EPA or the applicant(s) of the biological opinion — should a

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within 10 days of the deadline for issuing the opinion, the Service is entitled to an automatic 10-day extension on the deadline.

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

(7) Formulate a statement concerning incidental take, if such take may occur.

(8) In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data available and will give appropriate consideration to any beneficial actions taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation.

(h) Biological opinions. The biological opinion shall include:

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

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

(3) The Service's opinion on whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy biological opinion"); or, the action is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion). A "jeopardy" biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, it will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

50 C.F.R. § 402.14(g), (h).

Service choose option (b) or (c) (*i.e.*, non-wholesale adoption of EPA's effects determination) — is at EPA's option, rather than a mandatory part of the process. *See* 50 C.F.R. § 402.46(c)(3) (providing that "[t]he Service shall at the request of EPA or an applicant discuss with EPA and the applicant the Service's review and evaluation under this section"), *compare* 50 C.F.R. § 402.14(g)(5) (not couched in optional language).

Finally, the counterpart regulations expand the permissible use of the truncated "emergency" consultation procedures under 50 C.F.R. § 402.05 to cover all FIFRA section 18 actions,[2] effectively equating FIFRA emergencies with ESA emergencies.

D. Plaintiffs' complaint

Plaintiffs' complaint asserts seven causes of action, as follows:

(1) 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;

(2) 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;

(3) 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;

(4) 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;

(5) 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;

[2] FIFRA section 18 exemptions allow EPA to permit an otherwise unauthorized use of a pesticide in response to "emergency" conditions.

(6) EPA acted arbitrarily, 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;

(7) 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.

(Compl. *passim*.) Thus, Plaintiffs' complaint asserts both procedural and substantive challenges to the counterpart regulations.

Plaintiffs, the Services, and Defendant-Intervenors have all filed cross-motions for summary judgment.

III. ANALYSIS

A. Summary judgment standard

Rule 56 of the Federal Rules of Civil Procedure governs summary judgment motions, and provides in relevant part, that "[t]he judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). In determining whether an issue of fact exists, the court must view all evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248–50 (1986); *Bagdadi v. Nazar*, 84 F.3d 1194, 1197 (9th Cir. 1996). A genuine issue of material fact exists where there is sufficient evidence for a reasonable fact-finder to find for the non-moving party. *Anderson*, 477 U.S. at 248. The moving party bears the burden of showing that there is no evidence which supports an element essential to the non-movant's claim. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In order to defeat a motion for summary judgment, the non-

moving party must make more than conclusory allegations, speculations or argumentative assertions that material facts are in dispute. *Wallis v. J.R. Simplot Co.*, 26 F.3d 885, 890 (9th Cir. 1994).

B. Jurisdictional challenges to Plaintiffs' complaint

The Services and Defendant-Intervenors argue that the Court lacks jurisdiction to hear Plaintiffs' claims because Plaintiffs do not have standing to bring this lawsuit and because Plaintiffs' substantive challenges to the counterpart regulations are not yet ripe for consideration.[3] It is Plaintiffs' burden, at this stage of the litigation, to establish that there is no genuine issue of material fact remaining for trial regarding their standing and the ripeness of their claims. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (explaining that standing is not a "mere pleading requirement but rather an indispensable part of the plaintiff's case" and that "each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation").

1. Standing

To have standing, a plaintiff

> must show (1) it has suffered an "injury in fact" that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Citizens for Better Forestry v. USDA, 341 F.3d 961, 969 (9th Cir. 2003) (citing *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000)). By "particularized," the Supreme Court "mean[t] that the injury must affect the plaintiff in a personal and individual way." *Lujan*, 504 U.S. at 561 n.1. Put more simply, a plaintiff must "allege (1) personal injury (2) fairly traceable to the defendant's allegedly unlawful conduct and (3) [that is] likely to be redressed by the

[3] The Services and Defendant-Intervenors concede that jurisdiction over Plaintiffs' procedural challenge pursuant to NEPA is proper.

requested relief." *Defenders of Wildlife v. EPA*, 420 F.3d 946, 956 (9th Cir. 2005).[4]

As Plaintiffs are organizations, Plaintiffs' members must meet the standing test. *See*, *e.g.*, *id.* at 956. Here, Plaintiffs' members "use the waters of Washington for recreation, fishing, and aesthetic pursuits" (Compl. ¶ 2), "engage in and obtain great enjoyment and benefit from observing, studying, and photographing wildlife, including threatened and endangered species" (Compl. ¶ 4), and "depend on fish as a natural resource and, until recent fisheries closures . . . generated hundreds of millions of dollars in personal income to the [Pacific] region through commercial fishing" (Compl. ¶ 8), among other things. These allegations regarding Plaintiffs' enjoyment of and interest in listed species "meet the criteria for demonstrating an adequate injury in an environmental case" *Defenders of Wildlife*, 420 F.3d at 957.

The Court begins by noting that with respect to the second and third prongs of the standing issue, the case at bar is virtually on all fours with *Defenders of Wildlife v. EPA*. The *Defenders of Wildlife* plaintiffs had alleged violations of ESA section 7(a)(2)'s substantive *and* procedural requirements. *Id.* at 957. In that case, the Ninth Circuit accepted the plaintiffs' contention that ESA "section 7 consultation ha[d] in the past led to mitigation measures by real estate developers . . . and ha[d] thereby protected listed species and their habitat." *Id.* at 956. In particular, the court noted that during consultation regarding the challenged decision transferring pollution permitting authority from the federal agency to a state agency, FWS field staff had registered "serious reservations about the proposed transfer" because "section 7 consultations regarding past pollution permits in Arizona had led to mitigating measures to protect species' critical habitat, and feared that, without such mandatory consultation, Arizona would issue permits without mitigating measures" and that "[a]s a result, there could be harm to certain listed species." *Id.* at 952. Accordingly, the court found that "[t]he alleged

[4] As the Court observed, *supra* note 3, the Federal Defendants and Defendant-Intervenors have conceded that Plaintiffs have standing for their NEPA challenge.

injuries are fairly traceable to the EPA's . . . decision. As alleged by [Plaintiffs], that decision will remove water pollution permitting decisions from the significant protections provided by section 7 [consultations]." *Id*. at 958.

In the case at bar, according to Plaintiffs' allegations, the counterpart regulations would remove the Services from NLAA/"not likely to jeopardize" determinations, resulting in the removal of "the significant protections provided by section 7." The counterpart regulations would diminish or delay section 7 "protections" in the case of "optional formal consultations" and FIFRA section 18 emergency pesticide registrations. *Lujan* requires that these allegations regarding causation and redressability be supported by "facts showing that those choices have been or will be made in such a manner as to produce causation and permit redressability of injury." 504 U.S. at 562. For the following reasons, the Court finds that Plaintiffs have adduced sufficient facts to satisfy their burden of proof as to their standing.

This Court has previously had occasion to address a lawsuit filed by the Washington Toxics Coalition, the Northwest Coalition for Alternatives to Pesticides, the Pacific Coast Federation of Fishermen's Associations, and the Institute for Fisheries Resources against EPA, seeking to compel EPA to conduct section 7 consultations regarding certain pesticides and their effects on listed salmon and steelhead. *Wash. Toxics Coalition v. EPA*, No. C01-0132C (W.D. Wash. filed Jan. 30, 2001). In that action, after having reviewed the record, the Court found that EPA's failure to initiate section 7(a)(2) consultations with NMFS with respect to 55 pesticides for which EPA's own reports showed potentially significant risks to listed salmonids and their habitat, yet which had ongoing approval and or registration, violated ESA section 7(a)(2). *Wash. Toxics Coalition v. EPA*, No. C01-0132C, Order (W.D. Wash. July 2, 2002). Perhaps more pertinent is the fact, noted by the Ninth Circuit in its opinion affirming this Court's orders, that EPA did not dispute that "scientific or competent declaratory evidence in the record

demonstrated a causal link between the 54 pesticide active ingredients at issue . . . and direct or indirect adverse effects on salmonid populations." *Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1029 (9th Cir. 2005). Accordingly, the Court finds that the record shows that EPA's continued registration of at least 54 pesticides without having satisfied its consultation obligations under the general consultation regulations has a causal link to direct or indirect adverse effects on listed species.

Second, the administrative record is threaded through with consistent criticisms by Service personnel of EPA's proposed assessment process. Most remarkable is that the tenor of these criticisms did not change throughout the entire time during which the Services and EPA supposedly were working together to come up with an ESA-compliant effects determination process. The substance of these critiques is discussed more fully in Section III(E), *infra*, addressing the merits of Plaintiffs' claims.

Perhaps more pertinent for the purposes of the standing analysis, many of the concerns that arose during the programmatic discussions had been voiced before by Service scientists in the context of specific pesticide registrations or interim registrations. (*See*, *e.g.*, FWS 000720, FWS Letter to EPA re: Diazinon at 4 (July 20, 2000) (noting that sublethal effects of diazinon were a major concern); FWS 020627, FWS Letter to EPA re: Atrazine at 3 (June 27, 2002) (stating "EPA's pesticide risk assessments do not address several other important data gaps, including" (1) sublethal effects; (2) use of surrogate species; and (3) "inert" ingredients and adjuvants); FWS 020726, FWS Letter to EPA re: Endosulfan at 4–6 (July 26, 2002) (raising the issue of EPA's failure to adequately consider sublethal effects, disapproving EPA's weak label requirements and warning EPA that its acceptance of manufacturer-submitted studies in support of reregistration — 78% of which did not conform to EPA's own guidelines — "suggests that EPA may be unable to make a science-based decision" and that "the failure of EPA to require manufacturers to adhere to EPA requests 20 years [after EPA identified some of the same data gaps in a previous risk assessment] raises serious questions about data adequacy and

the usefulness of EPA's overall assessment") .)

By June 2004, the Services' concerns had neither changed nor abated. A draft NLAA nonconcurrence letter circulated by NMFS personnel, in which the Northwest Region Washington State Office ("WSO") of NMFS reviewed the draft biological evaluations and requests for concurrence with EPA's "may affect, not likely to adversely affect" determinations with regard to 28 pesticide registrations, noted almost identical categorical concerns with EPA's assessments.[5] (NMFS 5185, Draft Ltr. re: NLAA Nonconcurrence (June 7, 2004).) More pertinent is the fact that

> NOAA Fisheries does not concur with EPA's effects determinations. NOAA Fisheries believes the proposed actions, which includes [*sic*] registrations/reregistrations of active ingredients, formulated products . . . and mixtures . . . , will have greater than discountable or insignificant effects on listed species. NOAA Fisheries has determined that the proposed actions are "likely to adversely affect" the 26 ESUs and thus, require formal consultation.

(*Id.*) The Court is particularly impressed by the fact that of EPA's 28 requests for concurrence, the WSO concurred with *none* of EPA's NLAA determinations. This letter is direct evidence of a link, if such evidence were necessary, between the Services' criticisms of EPA's risk assessment process and the disparity between the results yielded by a typical EPA assessment and a Service study.

Despite the Services' consistent systematic criticism of EPA's risk assessment process, the final procedure agreed to by the Services did not address these long-observed problems. Because Plaintiffs contend that EPA's new risk assessment process contains the same defects as those observed by the Services prior to promulgation of the counterpart regulations, and because there is evidence on the record that EPA's former process resulted in determinations with which the Services could not concur,

[5] As explained by Plaintiffs, WSO identified the following grounds for its nonconcurrence: (1) its "concern that EPA's effects analyses may not be conducted using the 'best scientific and commercial data available' (NMFS 5186); (2) the WSO's inability to identify the "action" proposed for consultation (the WSO was particularly concerned about the potential difference between the effect of an active ingredient on its own and an active ingredient when mixed with inert ingredients or other additives); (3) lack of baseline information about listed species spatial and temporal status; (4) lack of complete information about potential exposures, such as exposure to pesticides from residential use and other cumulative exposure; and (5) failure to consider direct sublethal effects beyond growth and reproduction. (Compl. ¶ 47.)

and because there is evidence that this former process has resulted in continuing adverse effects on listed species, the Court finds that under *Defenders of Wildlife v. EPA*, Plaintiffs have sufficiently alleged that the counterpart regulations will cause personal injury via adverse effects on listed species. In the words of the *Defenders of Wildlife* Court, "the alleged injuries are fairly traceable to the [counterpart regulations.] As alleged by [Plaintiffs], [the regulations] will remove [NLAA pesticide registrations] from the significant protections provided by section 7 [consultations]," 420 F.3d at 957, and diminish or delay section 7 protections in the case of optional formal consultations and FIFRA section 18 registrations.

Finally, as in *Defenders of Wildlife*, Plaintiffs' requested relief, which would result in reinstating the Services' consultative role, would restore the "significant protections provided by section 7 [consultations]." *Id.* at 957. Accordingly, the Court finds that Plaintiffs have sustained their burden of showing that they have standing to bring their substantive challenge to the counterpart regulations.

2. Ripeness

> [T]he ripeness requirement is designed "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties."

Ohio Forestry Ass'n, Inc. v. Sierra Club, 523 U.S. 726, 732–33 (1998) (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 148–49 (1967)). The ripeness analysis is comprised of two prongs: (1) "fitness of the issues for judicial decision," *id.* at 733 (citations omitted); and (2) "hardship to the parties of withholding court consideration," *id.*

In determining whether the issues are fit for judicial decision, a court looks to whether the controversy presented is "definite and concrete," as opposed to "hypothetical or abstract." *Assiniboine & Sioux Tribes of the Fort Peck Indian Reservation v. Bd. of Oil & Gas Conservation of Mont.*, 792

F.2d 782, 788 (9th Cir. 1986) (citing *Babbitt v. United Farm Workers*, 442 U.S. 289, 298 (1979)). The *Assiniboine* Court further clarified that "[r]eview is not premature if the agency action is final, and is 'purely legal.'" *Id.* at 798 (citing *Abbott Labs.*, 387 U.S. at 149). In that case, involving one entity's abdication of its role in fact-finding and drawing initial conclusions, the court found that even if no actions had been taken as a result of or subsequent to the abdication of responsibility, the district court would have still been in a position to decide the merits of the plaintiffs' challenge to the abdication. *Id.* Fitness may be lacking, however, if "judicial intervention would inappropriately interfere with further administrative action" or if the reviewing court "would benefit from further factual development of the issues presented." *Ohio Forestry*, 523 U.S. at 733.

The relevant facts of this case are roughly analogous to the facts of *Assiniboine*. Here, Plaintiffs have challenged the Services' promulgation of counterpart regulations, which Plaintiffs allege are an effective abdication of the Services' consultative responsibilities in FIFRA actions.

This case is not like *Ohio Forestry*, on which the Services rely, and in which the plaintiffs challenged the Forest Service on its promulgation of a management plan which would permit logging activity to increase but which did not itself actually authorize the cutting of any trees. 523 U.S. at 729. In that case, the Supreme Court found that the Sierra Club's challenge was non-justiciable because it did "not find a strong reason why the Sierra Club must bring its challenge now." *Id.* at 734. The Supreme Court reasoned that before actual logging would be allowed, the Forest Service still had a number of procedural steps to complete, one of which required it to "permit the public [including the Sierra Club] an opportunity to be heard." *Id.* Most importantly,

> [t]he Sierra Club thus will have ample opportunity later to bring its legal challenge . . . . Any such challenge might also include a challenge to the lawfulness of the present Plan if (but only if) the present Plan then matters, *i.e.*, if the Plan plays a causal role with respect to the future, then-imminent harm from logging.

Id.

If this case were to be analogous to *Ohio Forestry*, Plaintiffs would have had to sue EPA. However, Plaintiffs have very specifically asserted claims only against the Services. Thus, unlike the Sierra Club in *Ohio Forestry*, if Plaintiffs do not or are not allowed to challenge the Services at this stage, Plaintiffs may not have another chance to challenge the Services for having promulgated the counterpart regulations. For example, because the counterpart regulations permit EPA to make NLAA determinations without informal consultation of or written concurrence from the Services,[6] should Plaintiffs wish to challenge an NLAA determination in the future, they may only assert this claim against EPA because the Services will have had no role in making this determination. In this respect, Plaintiffs are correct when they argue that the thrust of the Services' motion with respect to ripeness "describe[s] a different cause of action against a different defendant." (Pls.' Reply 5.) Here, Plaintiffs' lawsuit challenges the Services' abdication of their consultative role in FIFRA actions, not EPA's role in adopting the counterpart regulations or EPA's decision regarding any particular registration.

The record shows that the counterpart regulations, labeled "Final Rule" are, indeed, final. The removal of the Services from the consultation process was triggered by adoption of the ACA on August 25, 2004. Even if the Services or EPA were to determine that the ACA should be terminated, thereby restoring the Services' role in some fashion, NLAA determinations made while the ACA had been in effect would continue to be considered valid. 50 C.F.R. § 402.45(c). Therefore, the Court finds that the counterpart regulations are sufficiently final to support a finding of ripeness.

No party disputes that the issues presented are "purely legal" for the purposes of the ripeness analysis. However, the Services correctly point out that finality and the "purely legal" nature of the issue may not, alone, justify judicial review of a regulation where that review might inappropriately interfere with further administrative action, or where the Court might benefit from further factual

[6] Although the counterpart regulations permitted this only on the contingency that EPA entered into a suitable Alternative Consultation Agreement, EPA has done so, thereby removing the Services from NLAA cases altogether.

development of the issues presented. With respect to the latter concern, the Services point to *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158 (1967), in which the Supreme Court, acknowledging that "there can be no question that this regulation . . . is a 'final agency action' . . . [and] that the issue as [the plaintiffs] have framed it presents a purely legal question" nevertheless found that "judicial appraisal . . . is likely to stand on a much surer footing in the context of a specific application of this regulation than could be the case in the framework of the generalized challenge made here." 387 U.S. at 164–65.

This case is unlike *Toilet Goods Association* (and *Ohio Forestry*) in that the regulation being challenged here does not set the stage for a specific kind of action to follow. In *Toilet Goods Association* and *Ohio Forestry*, the plaintiffs challenged the promulgation of a regulation that paved the way for a specific type of action, permitting inspection of facilities and data, and permitting logging of more land, respectively. The Sierra Club in *Ohio Forestry* challenged the land management plan as "wrongly favor[ing] logging and clearcutting." 523 U.S. at 731. The plaintiffs in *Toilet Goods Association* challenged a regulation giving the FDA Commissioner free access to the plaintiffs' facilities In each case, the court found that a sample application of the regulation (*i.e.*, further factual development) would provide helpful data. The *Toilet Goods Association* Court explained:

> The regulation serves notice only that the Commissioner may under certain circumstances order inspection of certain facilities and data, and that further certification of additives may be refused to those who decline to permit a duly authorized inspection until they have complied in that regard. At this juncture we have no idea whether or when such an inspection will be ordered and what reasons the Commissioner will give to justify his order.

387 U.S. at 163. The Court added that the necessary inquiry would have to look into "what types of enforcement problems are encountered by the FDA, the need for various sorts of supervision in order to effectuate the goals of the Act, and the safeguards devised to protect legitimate trade secrets." *Id.*

In contrast, the regulation here *is* the action being challenged. The regulation itself effects a significant change in the Services' involvement in FIFRA actions, and it is *this* change that is protested

by Plaintiffs, not its effect on future pesticide registrations or re-registrations (although it could be fairly said that Plaintiffs protest the change *because* of its expected future effects).[7] As a result, the Court does not perceive, nor do the Services or Defendant-Intervenors identify, any cognizable benefit to waiting for further factual development.[8] Further factual development would shed no additional light on whether the Services' alleged abdication of their section 7 consultative role was legally proper because the inquiry in this case is whether the Services acted arbitrarily and capriciously when, *on the basis of the record already before them*, they made the decision to promulgate the counterpart regulations. Therefore, the Court does not find that the potential benefit of additional factual development justifies delaying review of this final action.[9]

In addition, the Court does not find that judicial review at this point will inappropriately interfere with further administrative action. The *Ohio Forestry* Court, which suggested that courts consider this factor, reasonably suspected that premature review of the forest plan would deny the agency the opportunity to correct its mistakes and to apply its expertise in so doing because of history

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[7] The Services characterize Plaintiffs' argument thus: "Plaintiffs' central argument is that EPA's risk assessment process will not work and that, as a result, the counterpart regulations will allow EPA to make effects determinations that do not comply with ESA." (Fed. Defs.' Opp'n 9.) Although this characterization captures part of Plaintiffs' argument, it fails to recognize that the thrust of Plaintiffs' Complaint in this lawsuit is that the *Services' abdication of their consultative responsibility permitting* EPA to make non-ESA-compliant effects determinations is itself non-ESA-compliant and was arbitrary and capricious.

[8] The Services suggest that "in the present case, applying the counterpart regulations will require EPA to first focus on particular pesticides and prepare effects determinations addressing specific species and locations." (Fed. Defs.' Reply 4.) However, materials prepared by EPA are irrelevant to the issue of whether removing the Services from their consultative role violates the ESA.

[9] In any case, there is already a substantial body of data available regarding the relationship between EPA failures to consult on pesticides and the adverse effects of the registration of those pesticides on listed species. *See*, *supra*, at 13–15. The Federal Defendants submitted for the Court's review a recently decided Ninth Circuit case, *Earth Island Institute v. Ruthenbeck*, No. 05-16975, slip op. 9317, 9328–31 (9th Cir. Aug. 10, 2006), pertaining to ripeness. The *Earth Island* Court found itself addressing the question of whether a challenge to regulations governing review of decisions implementing forest plans was ripe where the challenged regulations had not yet been applied to a specific case. The *Earth Island* Court found that further factual development was needed before a decision could be rendered because "[t]he record is speculative and incomplete." *Id.* at 9331. In contrast, in the case at bar, although the counterpart regulations have not been applied, the particular facts and circumstances of this case and the provenance of the regulations themselves have ensured a very full factual record requiring no speculation at all as to the regulations' effects. Accordingly, the Court does not find that *Earth Island* prevents a finding of ripeness in this case.

indicating that further consideration would actually occur before the Plan was implemented. 523 U.S. at 735. In contrast, in the present case, the Court is not aware of any such history relevant to the kind of regulation in question. Furthermore, the specific effect of the counterpart regulations, removing a potential dissenting voice from EPA effects determinations, makes it *less* likely rather than *more* likely that future developments will inspire the Services to reconsider and "correct" the counterpart regulations, if necessary. The practical effect of the regulations, which removes the Services from part of the FIFRA loop, is to make it difficult for the Services to remain apprised of and involve themselves in policing EPA FIFRA determinations — a likely necessary element of an effort to re-calibrate the counterpart regulations. For these reasons, the Court does not find that judicial review of the counterpart regulations will inappropriately interfere with further administrative action.

Accordingly, the Court finds that the issues presented are fit for judicial review.

The second prong of the ripeness analysis considers hardship to the parties of withholding court consideration. The Ninth Circuit has recognized that *Ohio Forestry* "answers [the hardship question] differently depending on whether a substantive or procedural challenge is made." *Citizens for Better Forestry v. Dep't of Agric.*, 341 F.3d 961, 977 (9th Cir. 2003). In the case of a substantive challenge to a substantive rule or regulation, such as in *Ohio Forestry*, no hardship occurs until a site-specific implementation. 523 U.S. at 733–34. In the case of a procedural challenge (*e.g.*, a claim that the NEPA procedure was not adequately followed), whether it be to a substantive or a procedural rule or regulation, the injury occurs at the time of the alleged procedural failure. *Id*. at 737 (explaining, for example, that "a person with standing who is injured by a failure to comply with the NEPA procedure may complain of that failure at the time the failure takes place, for the claim can never get riper").

Generally speaking, Plaintiffs assert that their challenge to the counterpart regulations is a procedural challenge and therefore that hardship is irrelevant (or, in the alternative, has already

occurred). In contrast, the Services and the Defendant-Intervenors argue that Plaintiffs' challenge is to the substance of the counterpart regulations. Although Plaintiffs do assert a procedural claim, the bulk of their claims challenge the substance of the counterpart regulations as non-ESA-compliant. However, because the counterpart regulations are themselves a procedural measure, rather than a substantive one like the forest plan challenged in *Ohio Forestry*, Plaintiffs' claim as to the substance (that is, as to the merits) is, ultimately, that the counterpart regulations work a procedural harm.[10] In other words, Plaintiffs' complaint effectively alleges two types of procedural harm at two different levels: (1) the Services, in promulgating the counterpart regulations, failed to follow NEPA procedures; and (2) the counterpart regulations themselves effect a procedural harm.

Thus, under *Ohio Forestry* and the Ninth Circuit's interpretation of that case in *Citizens for Better Forestry*, the injury to Plaintiffs, because it is a procedural one, has already occurred by the very promulgation of the counterpart regulations. Accordingly, the Court finds that withholding review would exacerbate the hardship that already exists and that this matter is ripe for review.

C. Standard of review for agency action

The Court's review of the Services' promulgation of the counterpart regulations is governed by the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2). Under the APA, the Court may "hold unlawful and set aside" agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). "An agency action will survive arbitrary and capricious review if it is rational, based on consideration of the relevant factors and within the

[10] The Services and the Defendant-Intervenors both cite to cases in which courts have found that substantive facial challenges to programmatic decisions are not ripe. However, these cases address substantive challenges to substantive rules, rather than substantive challenges to procedural rules. For example, in *Neighbors of Cuddy Mt. v. Alexander*, 303 F.3d 1059, 1067–68 (9th Cir. 2002), the court acknowledged that a challenge to a Land Resources Management Plan ("LRMP"), or a forest-wide plan, would not be ripe. However, both the *Neighbors* Court and the *Ohio Forestry* Court, in discussing LRMPs, make it clear that LRMPs are substantive in nature, even if they operate at a higher level than the site-specific plans governed by the LRMPs. The other cases cited, like *Neighbors*, were squarely governed by the outcome in *Ohio Forestry* and therefore inapposite to the present case.

scope of the authority delegated to the agency by the statute." *Defenders of Wildlife*, 420 F.3d at 959 (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42–43 (1983) (internal quotes omitted)). However, an agency action may be deemed arbitrary and capricious if

> the agency has relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id. Most relevant to the present case is that "[a]gency actions may not, of course, be inconsistent with the governing statute." *Id.* (citing 5 U.S.C. § 706(2)(A) instructing courts to "set aside" agency action "not in accordance with law").

D. Standard of review for facial challenges to regulations

The parties disagree as to whether the counterpart regulations are reviewable under the standard set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984) or the more stringent "no set of circumstances" standard articulated in *United States v. Salerno*, 481 U.S. 739, 745 (1987). As explained by the Ninth Circuit, "*Chevron* . . . established the rule that when Congress has left a gap in a statute and authorized a federal agency to fill that gap, the agency's interpretation is to be accorded deference as long as it is a 'reasonable' interpretation of the statute." *Van Tran v. Lindsey*, 212 F.3d 1143, 1151 (9th Cir. 2000). Thus, *Chevron* establishes a two-part analysis under which a court determining whether an agency regulation is inconsistent with its governing statute must (1) "ask whether Congress has directly spoken to the precise question at issue" and if so, whether the regulation comports with the clear meaning of the statute; and (2) if "the statute is silent or ambiguous with respect to the specific issue, [it] must ask whether the regulations promulgated by the agency are based on a permissible construction of the statute." *Akhtar v. Burzynski*, 384 F.3d 1193, 1198 (9th Cir. 2004).

In contrast, under *Salerno*, it appears that a court may invalidate a regulation only if no set of circumstances exists under which the regulation would be valid. 481 U.S. at 745 ("A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid."); *Reno v. Flores*, 507 U.S. 292, 301 (1993) (applying *Salerno* to challenges of regulations: "[T]o prevail in such a facial challenge, [the challenger] must establish that no set of circumstances exists under which the regulation would be valid.") (citing *Salerno*, 481 U.S. at 745) (alterations and quotes omitted).

Although the parties vigorously dispute the issue of which standard of review applies, none of the parties follow through on the notion that the two standards are not mutually exclusive.[11] In any case, the Court need not determine whether *Chevron* is trumped by *Salerno* because the contours of this particular challenge do not require it. Plaintiffs' claims are (1) that the very terms of the counterpart regulations themselves violate ESA section 7's command to federal agencies to consult with the Services; and (2) that the Services themselves, in promulgating the regulations, violated ESA section 7 by failing to ensure that the regulations were "not likely to jeopardize" listed species. If Plaintiffs are correct, then every application of the counterpart regulations necessarily violates the statute. Whether and how the regulations are applied are immaterial. In other words, if Plaintiffs' claims have merit, the arguably stricter *Salerno* standard is met and there would be no set of circumstances under which the counterpart regulations could be valid because their very terms violate the relevant statute.[12]

E. Merits

Plaintiffs seek to set aside the counterpart regulations under the APA as contrary to ESA section

[11] The Federal Defendants do point out that the standards "do not conflict but work together," but omit to engage in further explanation. (Fed. Defs.' Reply 11.) Nor does the case to which they cite for this proposition shed much light on how *Salerno* and *Chevron* are to be applied in tandem. *Babbitt v. Sweet Home Chapter of Cmtys. for a Great Oregon*, 515 U.S. 687, 699–700 (1995).

[12] For an exhaustive discussion of the relationship between *Chevron* and *Salerno*, see Stuart Buck, *Salerno v. Chevron: What to Do About Statutory Challenges*, 55 ADMIN. L. REV. 427 (2003).

7(a)(2) and to obtain a declaratory judgment that the Federal Defendants violated NEPA.

1. ESA challenges

Plaintiffs' ESA-based challenges focus on both (1) the counterpart regulations' substantive compliance with ESA section (7)(a)(2) (*i.e.*, do the processes outlined in the counterpart regulations satisfy ESA section 7(a)(2)?), and (2) the Services' compliance with the requirements of ESA section 7(a)(2) in promulgating the regulations (*i.e.*, did the Services "insure" that the counterpart regulations would be not likely to jeopardize?). The substantive challenges address NLAA determinations, optional formal consultation on LAA actions, and FIFRA section 18 registrations.

a. Regulations' substantive compliance with ESA section 7(a)(2)

i. NLAA determinations

Plaintiffs' first substantive challenge to the counterpart regulations is that ESA section 7(a)(2) prohibits the Services' delegation to EPA of their role in an NLAA determination.

In determining what Congress has enacted, the Court must begin with the language of the statute. *Akhtar*, 384 F.3d at 1198 (citing *Navajo Nation v. Dep't of Health & Human Servs.*, 325 F.3d 1133, 1136 (9th Cir. 2003)). The presumption is that "the ordinary meaning of the words chosen by Congress accurately express its legislative intent." *Brower v. Evans*, 257 F.3d 1058, 1065 (9th Cir. 2001). "The meaning of statutory language, plain or not, depends on context." *Id.* "Context" includes "the design of the statute as a whole and . . . its object and policy." *Id.* "In determining a statutory provision's meaning, [the Court] may consider the purpose of the statute in its entirety, and whether the proposed interpretation would frustrate or advance that purpose." *Id.* (citing *United States v. Mohrbacher*, 182 F.3d 1041, 1049 (9th Cir. 1999)) (quotations omitted).

The relevant language of ESA section 7 states: "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 listed species. As a point of departure, there is no dispute that this language requires an action agency to insure that any action authorized is not likely to jeopardize the continued existence of listed species.[13] CropLife characterizes the critical question as whether this language "flatly prohibits the delegation of NLAA authority to EPA." (CropLife's Reply 3.)

CropLife's elegantly simple statement of the question rather misses the point.[14] As the Services point out in their brief, "[i]ndeed, the 'not likely to adversely affect' standard is not even found in the ESA." While the Services make this point in an effort to show that section 7(a)(2) does not require consultation with and the assistance of the Services to reach an NLAA determination (because NLAA language is not to be found anywhere in the statute), what the point actually shows is that a finding of NLAA is not statutorily equal to a finding that an action is "not likely to jeopardize." In other words, an NLAA determination, standing alone, is not equivalent to a section 7(a)(2) determination made by an action agency "in consultation with and with the assistance of the Secretary" that an action is "not likely to jeopardize."

Because the NLAA concept is irrelevant to the actual statute, Defendants are correct insofar as they argue that the statute permits the Services to delegate their authority to participate in NLAA determinations. However, to the extent that Defendants' argument is also an argument that the Services may abdicate their consultative role in formulating the conclusion that an action is "not likely to

[13] As CropLife points out, Plaintiffs repeatedly misstate the "not likely to jeopardize" language as "will not jeopardize." (CropLife's Mot. 23.) However, as Plaintiffs' arguments do not rely on the inaccurate "will not jeopardize" language, the Court finds that these misstatements are immaterial. In addition, the Court finds it pertinent to note that although *TVA v. Hill*, 437 U.S. 153 (1978), from which Plaintiffs quote extensively, addressed an ESA that required agencies to insure "no jeopardy," and we are now operating under an ESA requiring only that agencies insure that an action is "not likely to jeopardize," *TVA v. Hill*'s strong rhetoric still lives. *See, e.g.*, *Sierra Club v. Marsh*, 816 F.2d 1376 (9th Cir. 1987).

[14] The Court notes that this conceptual formulation of the issue is joined in or assented to by all of the parties.

jeopardize," this argument requires further discussion.

Mandatory nature of "consultation"

The Services concede that section 7 contains a "requirement to act 'in consultation with and with the assistance of the Secretary'" (Fed. Defs.' Opp'n 25), but they and CropLife contend that the section's mandatory "shall" applies only to the substantive obligation to ensure that an action is not likely to jeopardize listed species (Fed Defs.' Opp'n 26; CropLife's Mot. 25–30).

This latter argument has been flatly rejected by the Ninth Circuit. In *Defenders of Wildlife*, the court stated that

> Section 7(a)(2) makes no legal distinction between the trigger for its *requirement* that agencies consult with FWS and the trigger for its *requirement* that agencies shape their actions so as not to jeopardize endangered species. . . . An agency's obligation to consult is thus *in aid of* its obligation to shape its own actions so as not to jeopardize listed species, not independent of it. *Both* the consultation obligation and the obligation to 'insure' against jeopardizing listed species are triggered by 'any action authorized, funded, or carried out by such agency,' and *both* apply if such an 'action' is under consideration.

420 F.3d at 961.

In the same vein, but broader, the Ninth Circuit has held generally that the ESA's procedural requirements are as important, and are mandatory to the same degree as its substantive requirements. The procedural aspects of section 7(a)(2), in which the consultation requirement appears, were discussed in the Ninth Circuit by *Thomas v. Peterson*, a case challenging the adequacy of an agency's investigation into the effect of a project on the endangered Rocky Mountain Gray Wolf. 753 F.2d 754, 763 (9th Cir. 1985). Although the district court had concluded that the agency had committed only an insignificant procedural violation, the Ninth Circuit disagreed. *Id*. at 763 (stating that the failure "goes beyond the technical violation cited by the district court and is not *de minimis*"). The court went on to explain: "The strict substantive provisions of the ESA justify more stringent enforcement of its procedural requirements, because the procedural requirements are designed to ensure compliance with

the substantive provisions." *Id*. at 764 (emphasis omitted). The Ninth Circuit has not backed off from the *Thomas* Court's position, repeating it in *Conner v. Burford*, 848 F.2d 1441, 1458 n.40 (9th Cir. 1988) and in *Forest Guardians v. Johanns*, 450 F.3d 455, 457 (9th Cir. 2006).

Put together and applied to this case, *Defenders of Wildlife* and the *Thomas* line of cases make it clear that ESA section 7(a)(2) requires that EPA, in contemplating even actions deemed NLAA, "consult" with the Services to ensure that its action be not likely to jeopardize listed species.[15]

Meaning of "consultation"

The Services argue that section 7(a)(2)'s injunction to consult "does not address whether an action agency like EPA can make its own 'not likely to adversely affect' determinations without further consultation with the Services." (Fed. Defs.' Mot. 25.) CropLife suggests that section 7(a)(2) "can be read as just requiring agencies to 'insure' against likely jeopardy through some process developed 'in consultation with and with the assistance of' the Service." (CropLife's Mot. 26.)

With respect to the first argument, advanced by the Services, the Court's holding that an NLAA determination is not equivalent to a section 7(a)(2) determination of "not likely to jeopardize" means that the ESA does not govern how NLAA determinations are to be made. In other words, Defendants are technically correct — NLAA determinations may be made unilaterally. What the ESA *does* do, however, is govern how an NLAA determination is to be converted into a proper ESA-compliant determination of "not likely to jeopardize." A unilaterally-made NLAA determination cannot be converted into a section 7(a)(2) finding of "not likely to jeopardize" without "consultation" with the

[15] Although the parties engage in some back-and-forth regarding how the consultation requirement is to be construed with respect to agency actions clearly and obviously without any impact on listed species (*e.g.*, the mailing of Social Security checks), this question is not before the Court and need not be decided. (CropLife makes a similar error of scope in characterizing Plaintiffs' argument as asserting that the counterpart regulations are *ultra vires* because they "delegate some Services' [*sic*] duties to EPA" — rather, the relevant issue is a narrower one.) The *Chevron* step-one inquiry is whether Congress has directly spoken to the *precise question* at issue. Here, the precise question is whether ESA section 7(a)(2) permits the adoption of a procedure by which an action agency may unilaterally determine that NLAA actions are also not likely to jeopardize listed species.

relevant Service.

With respect to the second argument, it is true that "consultation" is not defined in the statute. "Consultation" is defined in Black's Law Dictionary, in relevant part, as "[t]he act of asking the advice or opinion of someone (such as a lawyer)" or "a meeting in which parties consult or confer." BLACK'S LAW DICTIONARY (8th ed. 2004).

In addition to this ordinary dictionary meaning of the word, the Court must look to the statutory context in which it appears, including "the design of the statute as a whole and . . . its object and policy." *Brower*, 257 F.3d at 1065. In the present case, contrary to the Services' assertion that the statute does not "provide any direction or criteria" regarding how the consultation is to be carried out, the statute does contain some highly relevant provisions relating to consultation. First, the "in consultation with" language is paired with "with the assistance of the Secretary." This second part of the clause reinforces the notion that a section 7(a)(2) determination is not to be unilaterally made.

Second, section 7(b)(3)(A) states that after the conclusion of a section 7(a)(2) consultation, the Services "shall provide to the Federal agency . . . 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). Third, section 7(a)(2) itself concludes with the admonition that "[i]n fulfilling the requirements of this paragraph each agency shall use the best scientific and commercial data available." Both of these provisions, especially section 7(b)(3)(A), emphasize the rigor of the consultation contemplated by the statute.

In addition to these internal indicators of what is meant by "consultation," the Court cannot ignore that the ESA mandates that all federal agencies "shall insure" that their actions be not likely to jeopardize listed species.

In light of the ordinary meaning of "consultation," the ESA's internal express descriptions of

"consultation," and the ESA's substantive mandate, the Court does not find that with the use of the word "consultation" Congress left a "gap" to be filled by the Services. Although it may be true that "Congress left it to the informed discretion of the Services to define the *process of consultation*" (Fed. Defs.' Reply 12 (emphasis added)), Congress did not leave it to the discretion of the Services to define *consultation* in a way that results in no consultation at all on NLAA actions. In other words, while the wording of the statute and the statute's lack of granular direction on the process of consultation may leave it to the discretion of the Services to create a range of types of consultation, "shall . . . in consultation with" cannot be read as "no consultation on NLAA actions."

For these reasons, the Court cannot conclude that the plain meaning of "consultation" contemplates the joint creation of a process by which action agencies may unilaterally make the critical section 7(a)(2) determination regarding NLAA actions.[16] Accordingly, the Court finds that the portion of the counterpart regulations permitting no Service consultation on NLAA actions fails the *Chevron* step-one test and is therefore not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A). This portion of the rules must therefore be set aside. 5 U.S.C. § 706(2).

ii. Optional formal consultations

Plaintiffs' complaint also challenges the counterpart regulations as they relate to "optional formal consultations" (Compl. Count V). The "optional formal consultation" provisions permit EPA, as part of its effects determination to be included in a written request for consultation, to propose a jeopardy

[16] The Services contest Plaintiffs' characterization of the effect of the counterpart regulations as permitting unilateral self-consultation: "To the contrary, EPA and the Services have already consulted on this entire class of agency action." (Fed. Defs.' Mot. 26.) However, the Services cannot refute the fact that what was allegedly "consulted" on was a proposal to minimize or eliminate the Services' contribution to the determination of the "not likely to jeopardize" character of NLAA actions rather than the potential effect of NLAA actions and whether they may properly be deemed "not likely to jeopardize." Although the Services argue that the necessary connection between "NLAA" and "not likely to jeopardize" has been consulted on and approved (*i.e.*, it has been determined that NLAA actions, as a class, are "not likely to jeopardize"), the Court does not find that this "consultation" regarding an agreement *not to consult* satisfies the statutory "consultation" requirement as to NLAA actions.

conclusion and an incidental take statement that may then be adopted by the relevant Service. If the Service adopts EPA's effects determination, it may then issue a written statement doing so, converting EPA's proposal into a Service biological opinion and incidental take statement as required by the ESA. 50 C.F.R. § 402.46. If, on the other hand, the Service disagrees, it may modify EPA's effects determination or write its own biological opinion.

Plaintiffs state that "[t]he regulations make it relatively simple for the Services to adopt that effects determination as their biological opinion, while erecting additional procedural hurdles if the Services decide to deviate from the EPA draft." (Pls.' Mot. 16.) They further argue that "[b]ecause they are predicated on the Services' endorsement of EPA's risk assessments, the rule's optional formal consultation procedures also cannot be sustained." (*Id.* at 26 n.7.)

None of the parties address the optional formal consultation procedure at any length. However, it is clear that unlike the absolute recusal of the Services in the context of NLAA actions which plainly violated ESA section 7(a)(2)'s mandate to consult, the optional formal consultation procedure still preserves the Services' role. Indeed, though Plaintiffs may be right that the new procedure lowers the barriers to a Service's adoption of EPA conclusions and erects hurdles in the case of disagreement, there is nothing in ESA section 7(a)(2) that prohibits the shifting of burdens in this way. In addition, the Court notes that this alternative method of conducting and completing a "formal consultation" is "optional."

Because the Services remain free to amend or altogether reject EPA's effects determination in favor of a Service-authored biological opinion, thereby preserving and retaining their consultative role, the Court does not find that the optional formal consultation procedure is inconsistent with ESA section 7(a)(2).

iii. Emergency consultations on FIFRA section 18 registrations

The general consultation regulations permit an action agency, in "situations involving acts of God, disasters, casualties, national defense or security emergencies, etc.," to consult informally until "the emergency is under control," at which time formal consultation must be initiated, if necessary. 50 C.F.R. § 402.05. FIFRA section 18 permits EPA to exempt state and federal agencies from the provisions of FIFRA under "emergency conditions." 7 U.S.C. § 136p. The counterpart regulations permit EPA to "choose" to employ the emergency consultation procedures on FIFRA section 18 actions — in other words, permitting EPA to delay formal consultation on FIFRA section 18 actions.

Like the "optional formal consultation" provisions, the emergency consultation provisions are merely optional. Thus, EPA may simply choose not to take advantage of them, thereby preserving the status quo and not altering its consultation habits. However, even if EPA were to use the emergency consultation procedures to the maximum extent permitted under the counterpart regulations, the Court does not find that the temporal shifting of consultations that results is actually inconsistent with ESA section 7(a)(2). As the Court noted *supra* in its discussion of the optional formal consultation provisions, there is nothing in ESA section 7(a)(2) that prohibits the mere shifting about of consultations. Accordingly, the Court does not find that the counterpart regulation provisions regarding FIFRA section 18 registrations are inconsistent with ESA section 7(a)(2).

b. Services' compliance with ESA section 7(a)(2)

The parties appear to disagree as to whether the Services' action in promulgating the counterpart regulation is itself subject to ESA section 7(a)(2) — whether, in other words, the promulgation of the counterpart regulations constitutes an "agency action" under section 7(a)(2). The Court concludes that it does.

"Agency action" is defined by section 7(a)(2) as "any action authorized, funded, or carried out by" a federal agency." 16 U.S.C. § 1536(a)(2). In turn, the term "federal agency" is defined as "any

department, agency, or instrumentality of the United States." 16 U.S.C. § 1532(7).

For the purposes of section 7(a)(2), courts construe "agency action" broadly. *Pac. Rivers Council v. Thomas*, 30 F.3d 1050, 1055 (9th Cir. 1994). "An action is an 'agency action' if there is 'discretionary Federal involvement or control.'" *Marbled Murrelet v. Babbitt*, 83 F.3d 1068, 1073 (9th Cir. 1996). Discretionary involvement or control is found where an agency retains the ability to influence or change a given project. *Sierra Club v. Babbitt*, 65 F.3d 1502, 1509 (9th Cir. 1995). Here, as the promulgators of the counterpart regulations, the Services are undoubtedly free to alter or withdraw them. Therefore, the Court finds that promulgation of the counterpart regulations is an "agency action" within the meaning of ESA section 7(a)(2) and must comply with its terms.

Plaintiffs argue that the Services failed to comply with section 7(a)(2)'s mandates both to "insure" and to use the best science. According to Plaintiffs, the Services failed to insure that the counterpart regulations would be not likely to jeopardize in (1) permitting EPA to use an allegedly scientifically deficient process in its risk assessments, and (2) permitting EPA to invoke emergency consultation procedures across the whole range of FIFRA section 18 registrations. In addition, Plaintiffs argue that the Services, in signing off on EPA's proposed methodologies, themselves failed to use the best available science to insure that the counterpart regulations passed muster with ESA section 7(a)(2) (*i.e.*, that the counterpart regulations will be not likely to jeopardize).[17]

Plaintiffs urge that the counterpart regulations be set aside as the result of agency action not in accordance with the law.

i. "Insure"

[17] CropLife argues that ESA section 7(a)(2)'s "insure" duty falls on the action agency and suggests that Plaintiffs' effort to enforce the "insure" duty against the Services must fail because the EPA is the action agency. (CropLife's Mot. 37.) However, this argument fails to recognize that though EPA may be the action agency with respect to the actual FIFRA registrations, the *Services* themselves are the action agencies with respect to the adoption of the counterpart regulations.

ESA section 7(a)(2)'s mandate to agencies is plainly worded: each agency "shall . . . insure that any action . . . is not likely to jeopardize." Plaintiffs argue, in a nutshell, that the Services, in approving the counterpart regulations — namely (1) EPA's proposed risk assessment methodology and the NLAA process and (2) permitting emergency consultation procedures for the whole range of FIFRA section 18 registrations — failed to ensure that the counterpart regulations were "not likely to jeopardize."[18] For either of these arguments to succeed, Plaintiffs must establish a causal connection between the challenged procedure and risk of jeopardy to listed species. Furthermore, they must show that in concluding that the procedures satisfied the "not likely to jeopardize" standard of the ESA, the Services acted arbitrarily and capriciously.

EPA methodology & NLAA-to-"not likely to jeopardize" process

Counts II, III, and IV encompass Plaintiffs' complaints about the various manifestations of EPA's risk assessment procedures. Specifically, Plaintiffs contend that the process approved by the Services as functionally equivalent to a section 7 consultation is deficient in (1) failing to ensure that EPA considers the full range of scientific and technical data available; (2) permitting EPA not to consider formulations (*i.e.*, to ignore the effects of "inert" ingredients and other additives); (3) permitting EPA to use recognizedly insufficient surrogate species to fill data gaps; (4) permitting EPA not to consider sublethal effects other than reduced survival and reproductive impairment; and in the context of making NLAA determinations (5) permitting EPA not to consider the environmental baseline; and (6) permitting EPA not to consider indirect and cumulative effects.

Having reviewed the voluminous administrative record in this case, the Court finds that based on the evidence in that record, the Services' decision to permit EPA to make unilateral NLAA

[18] Plaintiffs presumably level the same charge against the provision regarding optional formal consultations. However, because the optional formal consultation procedure preserves the Services' role, Plaintiffs cannot establish a sufficiently close causal connection between the alleged deficiency and risk of jeopardy to sustain their burden of proof.

determinations and to permit those NLAA determinations to be equivalent to a finding of "not likely to jeopardize" was arbitrary and capricious. The Court's finding is based not only on the positive fact of the extremely strong technical and scientific evidence in the record demonstrating that approval of EPA's risk assessment process fails to "insure" within the meaning of ESA section 7, but also on the negative fact of the total absence of any technical and scientific evidence to support or justify the Services' approval of the process. Thus, this is not a case where there is merely "principled disagreement" between experts within the agency, *see, e.g.*, *Nat'l Wildlife Fed'n v. Norton*, 306 F. Supp. 2d 920, 929 n.15 (E.D. Cal. 2004), but one in which the agency experts were in *unanimous* agreement. Indeed, the administrative record is striking in its total lack of any evidence of technical or scientific support for the policy positions ultimately adopted by the Services in their sign-off letter and in the counterpart regulations.

Nor is this a case in which the final agency action reversed an "initial conclusion" reached by a small subset of individuals within the agency, *see*, *e.g.*, *Northwest Ecosystem Alliance v. FWS*, No CV03-1505, 2004 WL 1774559 (D. Or. Aug. 2, 2004), at *4. Unlike in *Northwest Ecosystem Alliance*, where the FWS was able to cite evidence contrary to the initial conclusion, not only were the conclusions here not merely "initial" but sustained over a long period of time and across several different contexts, but the Service policymakers who wrote the sign-off letter and approved the counterpart regulations also had no reasoned basis upon which to reject the advice of the technical team.

The record reflects a long history of disagreements between the Services and EPA and a general recognition inside the Services that the ESA and FIFRA have very different purposes. (*See*, *e.g.*, Jan. 10, 2003 E-mail from Don Knowles (NOAA) (NMFS 434–35) (noting that "we have a long and contentious relationship with epa for over a decade — they have started consultations under section

7(a)1, and then pulled out when we could not reach agreement").) The Court takes particular note of the fact that the specific problems identified by the technical team in EPA's risk assessment process already had been observed in the context of pre-counterpart regulation pesticide registration activities. For example, in the spring and summer of 2002, NMFS biologists had occasion to comment on EPA determinations regarding a number of pesticides. The comments generally identified shortcomings with EPA's consideration of the best available science, product formulations, and cumulative effects, as well as EPA's problem formulation and its use of the LC50 risk quotient. (*See*, *e.g.*, July 23, 2002 Comments by Rachel Friedman re: alachlor (NMFS 33–34); Aug. 20, 2002 Comments by Nathaniel Scholz re: propargite initiation package (NMFS 108–09).)

In March 2003, a technical team was formed to "produce a side-by-side comparison of EPA's risk assessment and labeling processes with the Service's effects determinations, conclusions, and mitigation consideration processes." (NMFS 1333.) "The purpose of this exercise [was] to identify potential gaps between the two processes and to identify potential ways of bridging these gaps, if any." (*Id.*) Right from the beginning, the team identified the following list of potential concerns:

1. Consideration of effects (sublethal, cumulative, synergistic, etc.).
2. Consideration of inerts, surfactants, degrades, etc.
3. Consideration of estimates of exposure (including increases in acreage; urban usage; drift models; etc.).
4. Consideration of Section 18 and Section 24c actions.
5. Assumptions regarding predictability of implementation and enforcement.
6. Assumptions about the use of surrogates.
7. Definitions of the action and action area.
8. Whether the information provided through EPA's risk assessment processes could be linked together in a BiOp appropriately to satisfy an APA standard of review.

(*Id.*)

Once the Service assessment was well underway and the team had had an opportunity to review EPA's risk assessment procedures, the team confirmed these concerns and repeatedly attempted to understand how the concerns could be mitigated or addressed. (*See*, *e.g.*, "Questions regarding EPA's

EFED Ecological Risk Assessment Process," (Apr. 6, 2003) (NMFS 1517–23); Apr. 28, 2003 E-mail from Don Knowles (NMFS 1607) (remarking "based on what we do know, we have a substantial disagreement with epa on the adequacy of their processes — such items as the issue of effects (indirect, etc), inerts versus actives, formulations versus actives, exposure estimates, toxicity endpoints, etc."); Aug. 26, 2003 Draft of Tech Team Comments (NMFS 2763–83); Sept. 5, 2003 Tech Team Comments (FWS 030905).)

Despite the consistent and persistent nature of the team's comments and suggestions regarding the non-equivalence between Service effects determinations and EPA's risk assessments, upper-level Service personnel signed off on EPA's risk assessment procedure as functionally equivalent (*i.e.*, providing the same level of protection to endangered species) to a Service analysis without addressing the vast majority of the technical team's concerns. While Defendants are correct that the issue is not whether EPA's process could be better, the issue is whether the Services arbitrarily and capriciously approved a process they knew would be less protective than the consultation process. Thus, the Court does not interpret the technical team's comments as an indictment of EPA's process, nor does the Court fault the sign-off letter's findings that many of the analyses performed by EPA represent the best it can do at this point in time. However, the Court *does* find that the uncorrected deficiencies pointed out in EPA's process beg the question of how the Services justified a finding that EPA's risk assessment *sans* Service concurrence would be as protective to listed species as the risk assessment accompanied by Service concurrence. EPA's risk assessment process is not only less protective than Service determinations, there is overwhelming evidence on the record that without a Service check, EPA risk assessments (leading to pesticide registrations) would actually result in harm to listed species.

As a preliminary matter, and as was noted over and over again by Service scientists, a Service effects determination and an EPA risk assessment have very different points of departure.

> The risk framework of FIFRA (no unreasonable adverse effects) does not equate to the survival and recovery framework of the ESA. The risk framework is driven by laboratory tests, models of exposure and occasionally some monitoring information. The ESA framework is an integration of status of the species, environmental background condition, the extent of the action within the action area, as well as laboratory and field testing, modeling and field validation. All of this information feeds into an analysis to support the purpose of the ESA to conserve ecosystems upon which threatened and endangered species rely.

(NMFS 1299.) As one comment explained another key difference between the Services' assessments and other action agencies' assessments:

> To prevent [jeopardy to species], the Services must treat evidence and uncertainty differently than most other agencies: to minimize risks to listed species, we conduct our analyses and navigate our decision-making processes to avoid false conclusions at each step of a consultation . . . (that is, the Services are biased to avoid the "false negative" conclusion or minimize the risk of Type II error).
>
> Most other agencies, including EPA, conduct their assessments in ways that avoid concluding that agency actions had adverse effects when, in fact, such a conclusion is false (that is, they are biased to avoid the "false positive" conclusion or minimize the risk of Type I error.

(NMFS 2577.)

Another Service comment addressing why consideration of cumulative effects is essential:

> Pesticide mixtures are the norm for many of our watersheds, and it is critical that baseline conditions (or background concentrations of other pesticides) be considered when evaluating the relative toxicity of a registered pesticide. This will be a major sticking point between ESA and FIFRA. Under ESA, the focus is on the species and, since salmon are exposed to pesticide mixtures, mixtures need to be included in the risk assessment. Under FIFRA, the focus is on the chemical and the registration of that chemical alone.

(NMFS 109.)

From a subject matter perspective, where the Services frame their analysis by looking at *species* and their relationships with the natural physical, biotic, and chemical environment, EPA's risk assessment frames its analysis with respect to an *active ingredient*. In other words, EPA's risk assessment, designed to answer a question posed by FIFRA (*i.e.*, whether unreasonable adverse effects would result from use of the pesticide), was not designed to answer the question posed by the ESA (*i.e.*,

whether an action may be considered "not likely to jeopardize").[19] Thus, it is not surprising that Service personnel identified significant gaps between the information generated during and by EPA's risk assessment process and the information generated during and by a Service effects determination. What is surprising is that, having acknowledged that these gaps exist, as well as the fact that Service analyses (because of the way they are framed) are more accurate and precise in terms of protecting listed species, the Services ultimately signed off on a largely unchanged EPA risk assessment as functionally equivalent to a Service effects determination.

One of the areas of major concern was EPA's screening models, particularly the GENEEC2 model for aquatic organisms, used to "identify [chemicals] which potentially pose sufficient risk to warrant more detailed modeling." (FWS 030905 at 4.) In particular, Service scientists were concerned that GENEEC2 underestimated exposure for several listed species "because model assumptions are frequently not consistent with the attributes of critical habitat for listed species." (*Id.* at 5.) For example, the model fails to account for uneven distributions of chemicals resulting from runoff or aerial drift. It also fails to account for the fact that many species pass some part of their lives in pools of water (*i.e.*, shallow puddles, vernal pools, muddy shoreline) significantly unlike the model pool. (*Id.*) Despite these known circumstances in which exposure estimates generated by GENEEC2 might be significantly underestimated, if the LOC for risk to non-target species is not exceeded, EPA "is confident that there is no risk of concern." EPA, OVERVIEW OF THE ECOLOGICAL RISK ASSESSMENT PROCESS IN THE OFFICE OF PESTICIDE PROGRAMS 41 (Jan. 23, 2004) [hereinafter EPA OVERVIEW]. Indeed, the Services' sign-off letter acknowledges the errors built into GENEEC2, but concludes that the model is still the best

[19] *See also*, NMFS 595 (draft comments re: EPA consultation initiation package on diazinon) (stating "[t]o summarize, the 'endangered species risk assessment' document for diazinon submitted by EPA contains critical gaps in the problem formulation phase. This is due to the fact that the assessment is predicated on an Environmental Risk Assessment developed for another purpose (*e.g.*, the registration of diazinon) in the context of an entirely different federal statute (FIFRA). Therefore, for the purposes of a section 7 consultation, the problem, assessment endpoints, and risk hypotheses should be revised and re-described.")

available approach for estimating aquatic exposure. (Sign-off Ltr. 15.)

GENEEC2 is of particular concern because Type II errors (false negatives)[20] generated by the model will result in unilateral NLAA/"not likely to jeopardize" determinations and will go uncorrected and unverified (*i.e.*, will proceed without Service concurrence about the effects conclusion) under the provisions of the counterpart regulations. Given that the sign-off letter itself acknowledges that GENEEC2 can underestimate exposure (thus resulting in a false conclusion that there is no risk of concern associated with a given chemical), yet approves an analytical process relying solely on GENEEC2 to provide information critical to making an NLAA/"not likely to jeopardize" determination, the Court cannot find that the Services in good faith "insured" that their approval of EPA's process would be "not likely to jeopardize" listed aquatic species.[21]

In the case of terrestrial organisms, Service scientists were concerned that EPA considered only the dietary exposure route even when other routes of exposure (inhalation from soil fumigants or dermal exposure for amphibians that respire through their skin) are the most logical pathway, and even though EPA's human health assessments consider these other routes of exposure. (FWS 030905 at 6.) In such cases, consideration of only the dietary exposure pathway may significantly underestimate risk to listed species. Again, because these exposure estimates are critical at the screening level, an underestimation at the screening level could result in no further ESA-relevant effects analysis being done before registration of a pesticide. Despite this, and despite acknowledging that exposure may also occur through inhalation or dermal contact, the Services signed off on a process that did not require EPA to

[20] In the discipline of statistics, significance testing can result in two kinds of errors, Type I and Type II. In the context of this case, a Type I error is one in which a pesticide is incorrectly determined to have an effect on listed species, while a Type II error is one in which a pesticide is incorrectly determined *not* to have an effect on listed species.

[21] Of course, an additional error factor that is external to the GENEEC2 model, and which will also tend to increase Type II errors at the initial screening-level assessment, is that EPA does not routinely consider mixtures of active ingredients (except in the case of terrestrial plants, EPA OVERVIEW 46) or the possibility that "inert" ingredients or other additives may affect the operation or effect of the active ingredient.

take into account information already available regarding alternate exposure pathways at the screening level. The Court finds that this, too, failed to "insure" that the counterpart regulations would be "not likely to jeopardize" listed species.

Also at the screening level, and apart from the possibility of underestimating potential exposure, the technical team was concerned about EPA's reliance on its system of comparing risk quotients to levels of concern ("LOC") to determine whether a pesticide warrants further analysis before an NLAA/"not likely to jeopardize" determination. As with the exposure models, the technical team was concerned that the relatively generic LOCs employed in many cases were inaccurate and could result in both Type I and Type II errors. (FWS 030905 at 7. *See also* NMFS 4325 (commenting that "[t]he assumptions that go into EFED's risk model do not provide an adequate screen for all listed species").)

In addition to their comments responding to the counterpart regulations, the record contains several examples of Service criticism of EPA's use of LOCs in the context of specific pesticide actions.[22] Although the team pointed out that EPA itself already uses a different comparison point (no-observed-effect-concentration ("NOEC") for certain categories (plants, chronic risk to fish and

[22] *See*, *e.g.*, NMFS 1584 (re: diazinon) (stating that "[t]he effects determination submitted by EPA does not adequately define the scientific basis for using the 'standard endangered species criterion . . . . A pesticide may have multiple modes of action (or toxicity), hence, justification is needed for using LC_{50} data as the sole means of determining toxicity, to the exclusion of essential physiological and behavioral systems of salmonids"); NMFS 112 (re: propargite); FWS 020627 at 3 (re: atrazine) ("Toxicity studies included by EPA in its final risk calculations for pesticide registrations often are limited to measures of acute mortality, or the pesticide concentrations at which short-term exposure will result in significant mortality in the test organism population. Due to this narrow focus, the ability of a pesticide to elicit a wide range of important sublethal effects often are not known. Furthermore, the Service believes that setting protective levels for pesticides in the environment based on their ability to prevent increased acute lethality is an inadequate level of protection"); NMFS 1931 (commenting that "[t]he recent publication of the effects determination for acrolein and impacts to salmonids states that there is a not likely to adversely effect [*sic*] partly based on uncertainty in being able to generate exposure values and determine risk quotients. The product has a high toxicity to fish, but because of the uncertainty in the exposure analysis a not likely to adversely effect [*sic*] was made."); NMFS 4583 (commenting "[t]o give you an idea of why I'm concerned, I've attached the risk assessment that was released last month to support the reregistration of creosote, which is highly toxic to fish . . . [quoting EPA] 'The toxicity of creosote to wildlife and plants is difficult to characterize as there is a very limited amount of data available that addresses that topic'").

wildlife),[23] the sign-off letter approved EPA's use of LOCs without consideration of available actual data from toxicology studies and other sources as "using the best available information [and] using it in an approved scientific manner." (Sign-off Ltr. 18.)

In addition, the technical team also questioned the narrow scope of EPA's inquiry, particularly its focus on the active ingredient alone. The Services were concerned that "the potential exists for a pesticide to cause additive, or synergistic toxicity when it co-occurs with other registered pesticides . . . . Multiple toxicity effects can be antagonistic, additive, or synergistic." (NMFS 594.) As with its LOC-related concerns, EPA's single-chemical focus had been a persistent source of concern for the Services. The record contains many instances in which the Services note that EPA fails to consider the environmental baseline (to account for existing stressors), mixtures and formulations (to account for the effect of other chemicals mixed with the active ingredient under review) and cumulative effects (to account for likely future events).[24] In a similar vein, Service scientists have had persistent concerns about EPA's inattention to the full spectrum of indirect effects and sublethal effects beyond growth and reproduction that could nevertheless impact species' survival.[25] Despite these repeatedly mentioned

[23] For example, the tech team suggested that "[t]he use of EC_0s . . . allows the risk assessment to be a function of the chemical and its properties as opposed to a one-size fits all level of concern." (FWS 030905 at 7.)

[24] *See*, *e.g.*, NMFS 108–09 (commenting on five no-effect determinations); NMFS 594 (comments on diazinon consultation initiation package); NMFS 1301; NMFS 2577–78; NMFS 5186 (draft non-concurrence letter re: 28 NLAA initiation packages).

[25] *See*, *e.g.*, NMFS 1876 (re: diazinon) (commenting that the full complement of chronic sublethal endpoints would consider "the quantity and quality of the prey base . . . , distribution and abundance of floating or submerged vegetation that provides cover for juvenile stages . . . reproductive behavior, reproductive success; migratory patterns, rates of growth in individuals, [and] the population dynamics of competitors and predators"); NMFS 5186 (draft non-concurrence letter re: 28 NLAA initiation packages); FWS 020514 (commenting that "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 alterations 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 strike; 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

issues, which tend to underestimate the risk posed by a pesticide, the Services ultimately approved a process that permits EPA to make a unilateral NLAA/"not likely to jeopardize" determination without considering these other factors, *even when the data is already available*. More important, the record does not reflect that the Services' approval, which ran counter to its scientists' consensus, was based on any science-based reason (*i.e.*, differences in scientific opinion). Indeed, the record contains evidence that at the time the Services issued their sign-off letter, they were aware that the foregoing problems with the scope of EPA's inquiry had played a part in the registration of two chemicals *known* to have highly toxic effects. (NMFS 1931 (re: acrolein); NMFS 4583 (re: creosote).)

The Court finds that in permitting EPA to disregard known deficiencies in the scope of its inquiry into a pesticide's effects, even where relevant data is already available, the Services failed to insure that the counterpart regulations would be "not likely to jeopardize" listed species.

In addition, in light of the persistence of the technical team's negative comments, and in light of the absence of any reasons or evidence in the record to support the Services' ultimate decision to disregard or discount the technical team's comments, the Court finds that the Services' approval of EPA's screening level processes as adequate to produce a reliable unilateral NLAA/"not likely to jeopardize" determination was arbitrary and capricious.

Even in cases in which the results produced by GENEEC2 or other screening models trigger further EPA evaluation, the technical team was concerned that several features of EPA's methodology in conducting this further evaluation would still result in frequent Type II errors. In addition to the continued effect of some of the defects at the screening level discussed above, the technical team manifested persisting concern regarding EPA's data-gathering, including the structure of its required toxicology testing protocols (also an issue at the screening level) and its strategy regarding the open

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eliminating all spawning for these species. In each of these examples EPA determined that their registration actions would either not affect these species or would not likely adversely affect them.").

scientific literature. The tech team was also concerned about the discretion given to FEAD (referred to as "professional judgment," EPA OVERVIEW 70) both in deciding whether an action is NLAA or LAA, and in "refining" the assumptions used at the screening level and potentially resulting in a screening-level "may affect" finding being converted into an NLAA/"not likely to jeopardize" determination.[26]

With respect to EPA's testing, Service scientists worried that the results of tests performed on surrogate species (as opposed to tests performed on the specific listed species) did not sufficiently take into account the significant uncertainties involved in accepting data from tests on one species as meaningful data about another species. EPA currently does not test reptiles and amphibians. Instead, it tests mallard ducks and bobwhite quails as surrogates for terrestrial-phase amphibians and reptiles, and bluegill sunfish, rainbow trout, and fathead minnows as surrogates for aquatic phase amphibians.

The Service scientists did not condemn the use of surrogates in an absolute sense — rather, they accepted the proposition that "in many instances, no specific data will exist concerning the effect of the pesticide in question on these classes of species, tests using surrogate species will likely constitute the best available information." (NMFS 3455 (FWS notes re: use of surrogate species).) However,

> [T]here can be great variability in the sensitivity of species to any given pesticide. EPA's overview of OPP's risk assessment process indicated that the "probability of capturing the most sensitive [bird] species is roughly 0.3%" when considering that only 2 avian species are required to be tested and there are 650 avian species in the US. Additionally, results among standard test species (e.g. the bobwhite and mallard) indicate that it's difficult to make generalizations regarding pesticide sensitivity as responses are often chemical specific and can vary by orders of magnitude even in closely related species . . . . [G]iven the uncertainty that exists when extrapolating between classes, the FWS believes it makes sense to suggest an even more conservative approach when extrapolating between classes. In addition, implementing extrapolation factors would provide registrants an incentive to address the uncertainty.[27]

(NMFS 3455–56.) *See also* EPA OVERVIEW 66.

[26] This feature of EPA's risk assessment process essentially gives pesticides another chance to overcome a "may affect" finding.

[27] Extrapolation factors, also referred to as safety factors, are essentially a discount rate applied to data from a surrogate species to take into account the possibility that data on a surrogate may not accurately represent the potential results from the same test on the actual listed species in question.

Despite these comments, and despite the fact that EPA expressly acknowledges the utility of safety or extrapolation factors in its overview document, EPA OVERVIEW 66–67 (even discussing the statistical meaning of different safety factors), EPA's process, as approved by the Services, does not require the use of such factors when surrogate data is used. One Service toxicologist noted that "[s]afety factors could really happen now if they wanted it to — safety factors are inherent to their process." (NMFS 4430.) A number of scientists noted that the use of surrogate data without the application of a safety factor greatly increased the possibility of risk to listed species. (*See*, *e.g.*, FWS 020514 at 2 (stating that "[t]he existing suite of tests have [*sic*] proven to provide little information of value in predicting potential effects to the many species listed under the ESA"); NMFS 2577 (explaining that "[o]ne of the main problems with surrogates is that we do not know if or to what degree the surrogates *ex situ* responses represent the *ex situ* responses of the species for which they are surrogates . . . . This problem becomes much larger when we try to make inferences about a species' *in situ* responses based on the surrogates *ex situ* responses."); NMFS 4325 (commenting that "EPA is essentially ensuring that data sets will continue to be inadequate for amphibians and reptiles by refusing to adopt uncertainty factors or add additional data requirements.").)

In light of the expressly acknowledged fact that safety factors would be more protective of listed species, and in light of the lack of any justification for allowing EPA's process to omit the use of safety factors, the Services failed to "insure" that the counterpart regulations, in permitting EPA not to apply more protective safety factors, was "not likely to jeopardize" listed species.

Also with respect to EPA's species-specific assessments, there was a broad consensus that EPA had failed to explain how it would go about searching for the relevant best available data. From the very beginning (*i.e.*, even prior to the inter-agency discussions regarding the counterpart regulations), Service scientists noted in the context of specific consultation initiation packages that EPA appeared to have

omitted to perform any routine searches of the available scientific literature for relevant data. For example, in a draft of a Service letter to EPA commenting on an initiation package for the chemical propargite, NMFS reminded EPA that, "[i]In the context of pesticides, the best available science includes the primary peer-reviewed scientific literature. It also includes the 'grey literature' such as agency technical reports and data submitted to the EPA by pesticide producers during the registration process." (NMFS 73 (Aug. 20, 2002 Ltr. to A-J Williams).) Because EPA's initiation package for propargite contained information culled only from the propargite Reregistration Eligibility Document, NMFS commented that "[t]he RED does not necessarily consider the peer-reviewed (or open) scientific literature or other sources of information regarding the potential toxicity of a pesticide to salmonids or other nontarget aquatic organisms. Also, the RED will not contain data from studies published after the document was developed." (*Id.*)

In mid-October 2002, EPA and Service personnel began to discuss the issue of how to craft a literature search strategy that would satisfy the "best available science" standard. After a little disagreement at the beginning about whether the discussion should be about reaching agreement about what data constituted the best science or about reaching agreement on a search strategy (NMFS 235), the record shows that Service personnel began to work on a document coaching EPA on a literature search strategy (NMFS 243–46). An early draft of this document, titled "Guidance for Conducting Literature Searches for Section 7 Consultations," recommended that literature searches target several electronic databases as well as conduct paper-based searches. (NMFS 243–44.)

By March 2003, the topic of literature searches had receded in the interagency discussions and a Service comment on the ANPR complained that "EPA's use of 'scientific data' is extremely limited. While they do require that all registrant data be GLP-based, they completely ignore the peer reviewed literature or grey literature." (NMFS 1300.)

Eventually, EPA proposed that it would routinely search a database called ECOTOX. As explained in the counterpart regulations, "[t]he ECOTOX database is a comprehensive system, maintained by EPA's ORD, that provides information on chemical effects on ecological species." 69 Fed. Reg. at 47,747. In addition, "EPA committed . . . also to search the studies that had been submitted [for inclusion in ECOTOX] but not yet processed and those that were considered and rejected." (Fed. Defs.' Opp'n 33.)

Although EPA's commitment to search ECOTOX was an improvement, the Services commented:

> EPA does not obtain all relevant exposure data by using ECOTOX because ECOTOX is an effects-related database, not an exposure database . . . . [E]xposure is a fundamental piece of ecotoxicology and literature associated with exposure must be identified reviewed [*sic*] to adequately assess potential effects to listed species and their habitat to ensure that risk is not underestimated.

(NMFS 1807 (Minutes from May 19, 2004 EPA-NMFS Mtg.).) In addition, one scientist pointed out that although "a growing body of information demonstrates that terrestrial insects are an important part of juvenile and adult salmonid diets," ECOTOX does not search on terrestrial insects. (NMFS 1808.)

Furthermore, in an effort to explain and document the qualitative difference between EPA's ECOTOX search strategy and a broader search strategy, the Services conducted comparative test searches. In one such test, NMFS conducted a literature search on diazinon, salmon, and elements of critical habitat. The broader search (including four databases) yielded seventeen references, whereas the ECOTOX search (on the terms "diazinon" and "salmon") yielded only two references. (NMFS 3225.) The NMFS scientist conceded that the ECOTOX search "will potentially uncover more data than required by FIFRA regulation" but stated that it was "not likely to yield the best scientific and commercial data available." (*Id.*) In another example:

> It took me about 30 seconds to come up with several times the number of references than were in ECOTOX using just a single outside database . . . . A search in Toxline using the terms "fenvalerate" and "non-target" came up with 43 references, only 3 of which were in ECOTOX. A search of "fenvalerate" and "bird" produced blatantly applicable papers

> from major journals with things like ". . . fenvalerate toxicity in American kestrels. . ." in the title that were not in ECOTOX. I can't even begin to imagine how they're populating this database.

(NMFS 3374.) Another search comparing results from ECOTOX and three databases NMFS "would normally use in consultations" found that there was no overlap between the results from ECOTOX and the results from the NMFS sources. (NMFS 3433.) (*See also* NMFS 4970–71.)

In sum, one NMFS individual explained

> The information available through the ECOTOX online database and the larger holdings EPA gathers for ECOTOX or other specific projects is designed to gather data on the toxicology of individual chemicals on species of fish and wildlife (it also gathers information on plants, but has less depth on the toxicology of plant taxa). That knowledge base will help EPA resolve *some* of the questions about the toxicology of different compounds, but will not help EPA in decisions that require information on mixtures, interactions, indirect effects, or the biology and ecology of listed species (I use "*some*" because ECOTOX is not a definitive source of data on toxicities associated with mixtures or other interactions).
>
> EPA may assert that they can make defensible "no effect/may potentially affect" determinations without considering information on how a compound works in mixtures, through other interactions (for example, increased toxicities when an animal is stressed, in the presence of chemical cues from predators, etcetera), or through indirect exposure pathways. Similarly, EPA may assert that they don't need information on the biology and ecology of listed species and their critical habitats to make defensible "no effect/may potentially affect" determinations. However, EPA cannot make defensible "not/likely to adversely affect" determinations without this information
>
> As a result, ECOTOX will only provide part of the information that EPA will need for its determinations. Therefore, EPA will still need a literature search strategy that is designed to gather this information from sources other than ECOTOX. I don't know how they can meet this requirement without searching the open, scientific literature using search strategies similar to those we identified in our draft letter to EPA.

(NMFS 3501 (Dec. 4, 2003 E-mail from C. Johnson to C. Riley, R. Sayers, J. LaBissonniere, M. Boroja).)

Despite this clearly and cogently stated rationale for why EPA's ECOTOX-centered literature search could not adequately support a risk assessment intended to be functionally equivalent to a Service consultation, a draft of the sign-off letter circulated on December 8, 2003 (NMFS 3538–49) approved

EPA's search strategy as adequate. The final sign-off letter endorsed EPA's literature search strategy thus: "The Services agree that the search strategies used by MED to identify information for potential inclusion into the ECOTOX database will retrieve the vast majority of relevant literature on the toxic effects of pesticides to listed species." (Sign-Off Ltr. 12.)

This endorsement, as well as the entire section of the sign-off letter discussing "best science," is very finely crafted to avoid raising the issue of the necessity of information other than information on the toxic effects of pesticides on listed species. In essence, the sign-off letter endorses ECOTOX as "best science" only with respect to more or less direct toxic effects of pesticides on listed species, without mentioning that this body of knowledge represents only one part of the whole body of knowledge Service scientists unanimously regarded as essential to informing a sound determination.

Even where EPA proposes to consider biological, ecological and critical habitat information, the sources proposed for such information do not include the open literature. (Sign-Off Ltr. 12.)

As a result of these deficiencies, EPA's assessment, which may use the best available information with regard to the specific targeted questions it asks,[28] is not adequate and does not use the best available information or scientific methodology with respect to protecting listed species. Indeed, the record (and the above discussion) demonstrates that the question of protecting listed species is a wider question than whether a particular active ingredient has a more or less direct effect on that species. Accordingly, the Court finds that the Services, in approving EPA's assessment analysis as functionally equivalent to the

[28] The Court is not prepared to find that EPA's risk assessment is based on the best scientific and commercial data available. In particular, the Court is concerned about indications that EPA is well aware that some of the baseline assumptions informing its screening-level exposure models are neither accurate nor adequately protective of listed species, yet was unwilling to adjust its screening procedure on a case-by-case basis to take available known information into account. Even the Services' sign-off letter approving EPA's assessment speaks volumes in the random spots of silence therein. For example, with respect to EPA's exposure models, the Services note that the current model for aquatic exposure may underestimate risk in specific circumstances, but conclude that "the existing model represents the *best available approach currently producing data* for estimating aquatic exposure." (Sign-Off Letter 15 (emphasis added).) Nowhere do the Services state that this approach either represents or exploits the best available data. In addition, the record contains several notes indicating that ECOTOX is far from comprehensive, throwing into doubt even the limited assertion that EPA's strategy considers the best science with respect to the narrowly drawn issue of direct toxic effects to species. (*See*, *e.g.*, NMFS 3374; NMFS 3501.)

EPA assessment plus a Service concurrence, and in permitting EPA's assessment to result in a unilateral declaration that an NLAA action is "not likely to jeopardize," failed to comply with ESA section 7's mandate to insure that the counterpart regulations were themselves "not likely to jeopardize" listed species.[29] In addition, because the Services fail to provide any support for the positions taken in the sign-off letter, positions that were clearly inconsistent with, and sometimes actually contrary to the findings of the technical team, the Court finds that the Services acted arbitrarily and capriciously.

Although the Services and the Defendant-Intervenors suggest that the possibility of retooling EPA's risk assessment process and the Services' option to terminate the ACA upon a belief that EPA's process is not ESA-compliant may rectify any failure to "insure" in compliance with ESA section 7 (*see* ACA 5 (discussing "Procedures to ensure EPA incorporates advances in the science of ecological risk assessment in making ESA determinations regarding pesticides")), the ACA also provides that previously-made NLAA determinations may not be affected by any such actions (ACA 10). Thus, even were the Services to come to a realization that EPA's process had resulted in erroneous NLAA determinations, those NLAA determinations could not be challenged or disturbed. It is unclear what recourse any party might have in such a situation to compel EPA to reassess its NLAA determinations.

Therefore, the Court finds that in approving an effects determination process known to be deficient and unreliable in many ways, and in agreeing that determinations made pursuant to that process may not be disturbed once they have been made, the Services failed to "insure" that their actions were

[29] The Court feels compelled to note that there are disturbing indications in the record that the very structure of the Service–EPA cooperation was engineered (by EPA) to conceal or minimize the positional differences between the Services and EPA. (*See*, *e.g.*, NMFS 1399 (commenting re: "EPA's anxiety over written records"); NMFS 1505 (reporting to Service team that "[a]s a way thru the problem with us having a written exchange of views, I Xeroxed an [*sic*] handed out again last week the October draft comments . . . . I asked EPA and USDA to review the comments again and lets see if we can nail down their problem with written exchanges . . . . It is not our goal to undermine their litigation position, but equally it is our goal to conduct the consultations in compliance with our regs and to build a record in support of our efforts . . . . As you know, we (FWS and NMFS) have raised this as a concern for a while. Yesterday, we reached an agreement with EPA and USDA that we **have** to find a way to proceed with the exchange of written materials.").)

"not likely to jeopardize."

In sum, the Court finds that the Services acted arbitrarily and capriciously in deciding to promulgate the counterpart regulations in their current state, knowing of the substantial flaws in EPA's methodologies and knowing that these flaws were highly likely (if not certain) to result in an overall under-protection of listed species as compared to the general consultation regulations. In addition, the overwhelming evidence in the administrative record demonstrates that the Services failed to comply with their ESA section 7 mandate to "insure" that their actions were "not likely to jeopardize" listed species. Accordingly, the counterpart regulation provisions regarding NLAA determinations must be set aside under 5 U.S.C. § 706(2)(a).

FIFRA section 18 and "emergencies"

As with the subject of EPA's methodology, the question is whether with respect to FIFRA section 18 actions, the counterpart regulations have retained the overall degree of protection afforded listed species by the general consultation regulations. 51 Fed. Reg. 19,937 (June 3, 1986).

The parties' primary disagreement is whether situations treated by EPA as emergencies under FIFRA section 18 are also properly considered "emergencies" under the ESA and its implementing regulations. The parties are in agreement that the definition of "emergency" in the general regulations leaves some room for interpretation in its use of the word "etc." The Services' Consultation Handbook contains some internal guidance to Service personnel about when an "emergency" exists:

> An emergency is a situation involving an act of God, disasters, casualties, national defense or security emergencies, etc., and includes response activities that must be taken to prevent imminent loss of human life or property. 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.

FWS & NMFS, ENDANGERED SPECIES CONSULTATION HANDBOOK 8-1 (Mar. 1998) [hereinafter HANDBOOK]. Plaintiffs contend that neither the general regulations' definition nor the Service

handbook guidance permits the wholesale inclusion of the entire range of FIFRA section 18 actions, which include a large number of repeat exemptions[30] and situations involving a potential loss of revenue of 20 percent.

With respect to the repeat exemptions, one scientist commented to the drafting team that he "would still like the opportunity to argue about the legitimacy of using emergency consultation procedures on 'emergency registrations' that reoccur year after year." (FWS 031229b.) The response to this comment was that "requesting the same emergency exemption in repeated years would [not] normally qualify as an 'emergency.'" (*Id.*) This understanding was shared by EPA, as reflected in a document prepared by EPA in the middle of May 2003, describing EPA's thoughts on four "high-priority" issues. (NMFS 1813 (E-mail explaining document's context); FWS 030516b (proposing that "the Services and EPA agree on an interpretation of the current section 7 regulations that would treat all FIFRA emergency exemptions as 'emergencies' for the purpose of sec. 402.05, except 'specific exemptions' involving use of a pesticide for which an emergency exemption had been approved in the previous year for the same State or Federal agency to address the same pest control problem.").) Despite this early apparent consensus, by the time the final rule was published, EPA had the option of choosing the emergency consultation procedures over the entire range of FIFRA section 18 actions. 69 Fed. Reg. at 47,739–40.

The term "emergency" does not appear in the relevant sections of the ESA. The Federal Defendants are correct that the ESA itself does not prescribe how agencies should consult during an emergency, and that given this gap, the Services were obliged to fill the gap with rational regulations

[30] For example, in the state of California, thirteen of twenty-five section 18 exemptions in 2003 were repeats (same use site, same pests) from 2002. FWS 031212m. In another example, informally responding to a request for examples of pesticides registered under section 18 emergency procedures repeatedly for many years, one scientist named eleven pesticides "off the cuff." NMFS 3765. One such pesticide, flowable carbofuran, had been granted repeat exemptions as many as eight times in some states. *See also* FWS 030516b (commenting that "as a practical matter . . . 'repeat' exemptions constitute about 80% of the emergency exemptions each year.").

that themselves comply with ESA section 7. The 1986 general consultation regulations prescribed a course of action deemed suitable for emergencies. In so doing, the regulations suggested examples of what types of situations constituted emergencies (*i.e.*, "acts of God, disasters, casualties, national defense or security emergencies, etc."). 50 C.F.R. § 402.05. Although "emergency" was not actually defined, some guidance may be taken from the examples provided.

"Act of God" is defined in the dictionary as "[a]n overwhelming, unpreventable event caused exclusively by forces of nature, such as an earthquake, flood, or tornado." BLACK'S LAW DICTIONARY (8th ed. 2004). It is defined in the *Oxford English Dictionary* as the "action of uncontrollable natural forces in causing an accident, as the burning of a ship by lightning." OXFORD ENGLISH DICTIONARY (2d ed. 1989) ("OED"). *Black's* defines "disaster" as "a calamity, a catastrophic emergency," while the OED defines it as "[a]nything that befalls of ruinous or distressing nature; a sudden or great misfortune, mishap, or misadventure; a calamity." "Casualty" is defined as "[a] chance occurrence, an accident; *esp.* an unfortunate occurrence, a mishap; now, generally, a fatal or serious accident or event, a disaster," *Oxford English Dictionary*, and "1. A serious or fatal accident. 2. A person or thing injured, lost, or destroyed," BLACK'S LAW DICTIONARY.

In addition, "emergency" is defined in the dictionary as "a state of things unexpectedly arising, and urgently demanding immediate action." OXFORD ENGLISH DICTIONARY.

The overwhelming impression conveyed by these examples of "emergency" and by the general-purpose ordinary language meaning of "emergency" itself includes the element of surprise and unexpectedness. As a result, even though "emergencies" under the general consultation regulations may include situations which do not necessarily involve the potential loss of human life, but only of property, such "emergencies" must also be unpredictable or unexpected in some way. This definition of "emergency," supported both by its context in the regulation and by its ordinary meaning, does not

include those FIFRA section 18 actions involving repeat "specific" exemptions for the same pesticide for the same use site, especially where those specific exemptions have been granted for many years on end.

Indeed, although the section 18 implementing regulations begin by defining a section 18 emergency condition as "an urgent, non-routine situation that requires the use of a pesticide(s)", 40 C.F.R. § 166.3(d), the regulation continues, saying that an emergency condition

> shall be deemed to exist when . . . [t]he situation . . . [w]ill cause significant economic loss due to: (A) an outbreak or an expected outbreak of a pest; or (B) a change in plant growth or development caused by unusual environmental conditions where such change can be rectified by the use of a pesticide(s).

40 C.F.R. § 166.3(d). This latter part of the regulation effectively neuters the requirement that the situation be "non-routine" (an element akin to the unpredictability element in the general consultation regulations' understanding of "emergency") by mandating that an "emergency condition" *shall* be deemed to exist where significant economic loss is expected due to an outbreak of a pest, without requiring that the outbreak be unexpected or non-routine. Thus, under FIFRA, a situation may legitimately be considered an emergency and subject to section 18 without being "non-routine."[31] Accordingly, the Court finds that FIFRA's definition of "emergency," and ESA's definition of "emergency", while overlapping, are not equivalent to one another.

To come to the contrary conclusion, as the Services did in their counterpart regulations, and to treat *all* FIFRA section 18 emergencies as ESA emergencies is to be less protective of listed species

[31] Thus the issue of whether Plaintiffs are presuming that EPA will "abuse" FIFRA section 18 is immaterial. (*See* Fed. Defs.' Opp'n (arguing that EPA "is entitled to the presumption that it will 'act properly and according to law.'").) The language of the FIFRA section 18 implementing regulations *permits* EPA to make repeated findings of "emergency" as to the same pesticide for use on the same site.

than the general consultation regulations and to fail to comply with ESA section 7's mandate to "insure" that the counterpart regulations are "not likely to jeopardize" listed species.[32]

In addition to the failure to comply with ESA section 7, the Services also acted arbitrarily and capriciously in reaching the conclusion stated in the preamble to the counterpart regulations that "the overwhelming majority of FIFRA emergency exemption actions could properly be considered emergencies for the purposes of § 402.05." 69 Fed. Reg. at 47,739–40. Not only is it clear that the plain language of the applicable FIFRA regulations goes beyond the plain language of the general consultation regulations, *EPA itself* acknowledged that out of about 500 FIFRA section 18 actions each year, about 400 were repeat specific exemptions for pesticides on the same use sites. (FWS 030516b.)

The Federal Defendants point to no evidence in the record that contradicts or lessens the effect of the above factors. The Court's own perusal of the record revealed no evidence to support the conclusions stated in the counterpart regulations. Accordingly, the Court finds that the Services acted arbitrarily and capriciously in permitting EPA to use emergency consultation procedures for the whole range of FIFRA section 18 actions. The counterpart regulation provisions regarding emergency consultation procedures for FIFRA section 18 registrations must therefore be set aside pursuant to 5 U.S.C. § 706(2)(a).

ii. Best science

Plaintiffs contend that the Services, in promulgating the counterpart regulations, themselves failed to heed the best scientific and commercial data available. The Court need not address this

[32] This is not to say that no repeat specific exemptions can ever be eligible for an emergency consultation procedure. For example, a rule permitting emergency consultation for repeat specific exemptions in cases where EPA is undertaking its best efforts to initiate consultation, yet is unable to do so because of reasons beyond its control, would take into account the requirement that an "emergency" have an element of uncontrollability and unexpectedness.

argument as the relevant analysis would be largely redundant with the Court's discussion of the Services' failure to comply with the mandate to "insure."

2. NEPA challenge

The National Environmental Policy Act ("NEPA") "encourage[s] productive and enjoyable harmony between man and his environment . . . [and] promote[s] efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man." 42 U.S.C. § 4321. In pursuit of these lofty goals, NEPA establishes "action-forcing" procedures that force agencies to take a "hard look" at environmental consequences. *See Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 348 (1989).

NEPA requires that

> all agencies of the Federal Government shall . . . include in every recommendation or report on . . . major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on —
>
> (i) the environmental impact of the proposed action,
>
> (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
>
> (iii) alternatives to the proposed action,
>
> (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
>
> (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

42 U.S.C. § 4332. This statement is referred to as an environmental impact statement ("EIS"). In determining whether a federal action requires an EIS (*i.e.*, whether it is a "major" action "significantly affecting the quality of the human environment"), an agency must prepare an environmental assessment ("EA"), 40 C.F.R. § 1501.4(b), that "[b]riefly provide[s] sufficient evidence and analysis for determining

whether to prepare an [EIS] or a finding of no significant impact [("FONSI")]" and which also, among other things, briefly discusses the environmental impact of the proposed action.[33] 40 C.F.R. § 1508.9.

In the present case, the Services prepared an EA in which they found that the counterpart regulations would have no effect on the environment. Accordingly, the Services issued a FONSI. Plaintiffs challenge the EA's findings that the counterpart regulations would have no effect on the environment and contend that the Services should have prepared a full EIS. Plaintiffs also challenge the timing of the Services' NEPA compliance.

a. Timing

With respect to an agency's NEPA compliance, the Ninth Circuit requires that "the comprehensive 'hard look' mandated by Congress and required by the statute must be timely, and it must be taken objectively and in good faith, not as an exercise in form over substance, and not as a subterfuge designed to rationalize a decision already made." *Metcalf v. Daley*, 214 F.3d 1135, 1142 (9th Cir. 2000). NEPA's implementing regulations state that "[a]gencies shall integrate the NEPA process with other planning at the earliest possible time to insure that planning and decisions reflect environmental values, to avoid delays later in the process, and to head off potential conflicts." 40 C.F.R. § 1501.2. Accordingly, the Ninth Circuit has found that where an EA is prepared after making an "irreversible and irretrievable commitment of resources," the agency has acted in an untimely manner. *Metcalf*, 214 F.3d at 1143.

Here, the Federal Defendants do not deny that no mention of NEPA surfaces in the administrative record until April 2004. (FWS 040416.) This was about three months after the proposed counterpart regulations had already been published and the Services had already issued their sign-off letter. The

[33] Agencies need not prepare EAs if the proposed action is categorically one that requires or does not require an EIS. 40 C.F.R. § 1501.4(a).

EA was released on July 2, 2004, touching off a 21-day comment period.[34] On Saturday, July 24, 2004, the Services had already drafted a FONSI. (NMFS 5820.) The drafter of the FONSI did not know whether any comments had been submitted in response to the EA. (*Id.*) On Monday, July 26, 2004, after a flurry of e-mails commenting on the FONSI and reflecting that nobody knew whether any comments had been received, one individual finally informed the group that "[w]e have received a few comments on the EA and I believe that Defenders submitted comments to both NOAA and FWS." (NMFS 5912.)

The final counterpart regulations were signed by the Services on July 27, 2004, and the FONSI was signed by FWS on July 28, 2004, and by NMFS on July 29, 2004.

It is true that the Ninth Circuit in *Metcalf* disapproved of an agency's NEPA compliance where that compliance was performed after already having signed two agreements binding the agency to support the proposal at issue. 214 F.3d at 1142. Although the Federal Defendants in the present case attempt to differentiate the situation in this case on the basis that the counterpart regulations did not take effect until well after the FONSI had been issued, and also on the basis that the ACA permits the Services to terminate the operation of the counterpart regulations (and is therefore not binding), these arguments fail to account for the spirit of *Metcalf*.

The Ninth Circuit explained that "[t]he Federal Defendants did not engage the NEPA process 'at the earliest possible time.' Instead, the record makes clear that the Federal Defendants did not even consider the potential environmental effects of the proposed action until long after they had already committed in writing to support the Makah whaling proposal." *Id.* at 1143. In the court's preceding

[34] The administrative record reflects that the Services intended for the comment period to be thirty days (after some initial debate about a fifteen-day period). (*See* NMFS 5240.) However, after an unexpected 10-day delay in finalizing the draft EA and the notice thereof, the decision was made to shorten the comment period to 21 days. (NMFS 5497 (explaining "As a result of delays in getting the FR notice our [*sic*], we are running into a time constraint. Therefore we would like to change the comment period to 21 days.").)

discussion of the facts, it noted that the Makah had first asked the Federal Defendants for help in 1995, yet an EA was not prepared until 1997.

The facts here are not so qualitatively different. The timing of the Services' NEPA compliance strongly implies that it was an afterthought, rather than a bona fide attempt to gather information and to analyze the environmental consequences of its actions. Indeed, an e-mail from Julie MacDonald, the FWS deputy assistant secretary, stressed:

> Either the Service or NMFS (or some combination) will have to provide environmental documentation for the Pesticide Rule. I have tried unsuccessfully for over a month to get some information on where/who is working on this and what the timeline looks like. I cannot emphasize enough the urgency for completing this work. It would not do at all to have the rule completed and be unable to implement it due to the fact that the government did not finish the environmental work in a timely fashion.
> . . . .
> What is the fastest possible timeline for preparation of the NEPA documents
> . . . .
> I don't want this rule to be delayed because we did not do our NEPA work, and I don't want to miss any important APA steps.

(FWS 040416.) This e-mail strongly suggests that the Services did not engage in their NEPA obligations in good faith or with the intention of permitting input received from the NEPA process to influence their ultimate decision.

Although it may be true that the Services had not *bound* themselves to promulgation of the counterpart regulations, from a practical process point of view, they had gone beyond the point of no return. While this is not a case of absolute irreversibility, it is also not a case involving mere preliminary consideration or a mere identification of a preferred course of action. *Metcalf*, 214 F.3d 1145.

All the pieces other than the NEPA step were in place to finalize the counterpart regulations. The process of formulating the counterpart regulations had been going on for over a year before NEPA even became a concern (at least as reflected in the administrative record). There is absolutely no evidence in the record that indicates that any comment received during the NEPA process could have had any

influence on the Services' promulgation of the counterpart regulations. As in *Metcalf*, the Court finds that the timing of the Services' NEPA compliance "seriously impede[ed] the degree to which their planning and decisions could reflect environmental values." 214 F.3d at 1144 (quoting *Save the Yaak Comm. v. Block*, 840 F.2d 714, 718–19 (9th Cir. 1988)). "By the time the Federal Defendants completed the final EA . . . the die already had been cast." *Id.* at 1144. Such tardy NEPA compliance thwarts "NEPA's effectiveness [which] depends entirely on involving environmental considerations in the *initial* decisionmaking process." *Id.* at 1145 (emphasis added).

However, despite the strong rhetoric in *Metcalf*, the court limited its holding "to the unusual facts and circumstances of [that] case." *Id.* Accordingly, although the Court strongly disapproves of the noncommittal manner in which the Federal Defendants chose to perform their NEPA obligations, the Court does not find that the absence of any evidence of sincere interest or alacrity are sufficient for a finding that the Federal Defendants' manner violated NEPA under existing Ninth Circuit caselaw.

b. Substance of the EA

> In reviewing an agency's decision not to prepare an EIS under NEPA, [the Court] employ[s] an arbitrary and capricious standard that requires [it] to determine whether the agency has taken a "hard look" at the consequences of its actions, "based its decision on a consideration of the relevant factors," and provided a "convincing statement of reasons to explain why a project's impacts are insignificant."

Nat'l Parks & Conservation Ass'n v. Babbitt, 241 F.3d 722, 730 (9th Cir. 2001) (quoting *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998), and *Metcalf*, 214 F.3d at 1142).

> [A]n EIS *must* be prepared if substantial questions are raised as to whether a project *may* cause significant degradation of some human environmental factor. To trigger this requirement, a plaintiff need not show that significant effects *will in fact occur*; raising substantial questions whether a project may have a significant effect is sufficient.

Idaho Sporting Congress v. Thomas, 137 F.3d 1146, 1149–50 (9th Cir. 1998) (quotations omitted).

In sum, in order to prevail on their NEPA claim, Plaintiffs must show that the Services were arbitrary and capricious in determining that there was no substantial question that the counterpart regulations would have no significant effect on the environment.

The Court's review of the administrative record, and the analysis performed with respect to Plaintiff's ESA claims more than suffice to show that it should have been clear to the Services that there were substantial questions *supra* about the environmental effects of the counterpart regulations. Although the Services now defend their EA findings of no significant impact on the basis that they had found that EPA's process and Service consultations were functionally equivalent, the Court has already found in its discussion above that this finding was contrary to the record and arbitrary and capricious. Accordingly, the Federal Defendants may not now rely on "functional equivalence" to protect their EA and FONSI.

In any case, even if the "functional equivalence" opinion could be defended as a bona fide reasoned opinion, the virtual unanimity of the Service biologists' and toxicologists' criticisms of EPA and their litany of comments regarding the insufficiency of EPA's methods to protect listed species (as discussed *supra*) raises substantial questions about the potential impact of the counterpart regulations on the environment. The presence of this debate within the Services is sufficient to trigger the Services' obligation to prepare an EIS. *Sierra Club v. U.S. Forest Serv.*, 843 F.2d 1190, 1193 (9th Cir. 1988). Accordingly, the Court finds that Plaintiffs have borne their burden on their NEPA claims as to the NLAA provisions and the emergency consultation provisions.

This holding does not extend to the "optional formal consultation" portion of the counterpart regulations not set aside under 5 U.S.C. § 706(2)(a). Plaintiffs fail to show, and there is no evidence to suggest that the optional formal consultation provisions will have much effect, much less a significant effect, on the consultation process or its results. As the Court noted *supra*, the optional formal

consultation provisions permit the Services to choose whether or not to compose their own biological opinion and incidental take statement. If the Services disagree with an EPA draft, there is no Service obligation to adopt that draft. Accordingly, the Court does not find that the optional formal consultation provisions will have a significant impact on either the relationship between EPA and the Services or on the quality of the human environment.

In sum, the Court finds that the Services violated NEPA by failing to prepare an EIS considering all of the impacts of, and alternatives to, adoption of the NLAA and emergency consultation provisions of the counterpart regulations.

IV. CONCLUSION

In accordance with the foregoing, the Court hereby GRANTS Plaintiffs' motion for summary judgment with respect to the NLAA and emergency consultation provisions of the counterpart regulations and DENIES Plaintiffs' motion with respect to the optional formal consultation provisions. The Defendants' motions for summary judgment are GRANTED with respect to the optional formal consultation provisions and DENIED with respect to the NLAA and emergency consultation provisions.

The NLAA and emergency consultation provisions of the counterpart regulations issued by the Federal Defendants at 69 Fed. Reg. 47,732 (Aug. 5, 2004) are arbitrary and capricious, and contrary to law as set forth above. The Federal Defendants violated NEPA by failing to prepare an EIS properly considering all of the impacts of, and alternatives to, adoption of these provisions.

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Accordingly, the Court hereby ORDERS that the NLAA and emergency consultation provisions be set aside and that the Federal Defendants be enjoined from implementing these provisions.

SO ORDERED this24th day of August, 2006.

UNITED STATES DISTRICT JUDGE