IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

CENTER FOR FOOD SAFETY; KAHEA; FRIENDS OF THE EARTH, INC., and PESTICIDE ACTION NETWORK NORTH AMERICA, Plaintiffs, vs. MIKE JOHANNS, Secretary, U.S. Department of Agriculture; WILLIAM T. HAWKS, Under Secretary of Agriculture for Marketing and Regulatory Programs; BOBBY R. ACORD, Deputy Administrator, U.S. Department of Agriculture, Animal and Plant Health Inspection Service and CINDY SMITH, Deputy Administrator, U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services Program, Defendants.	)	CIV. NO. 03-00621 JMS/BMK ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

From 2001 to 2003, four companies -- ProdiGene, Monsanto, Hawaii Agriculture Research Center (HARC), and Garst Seed -- planted corn and sugarcane that had been genetically modified to produce experimental pharmaceutical products. The companies modified the genetic structure of the corn or sugarcane so that, when harvested, the plants would contain hormones, vaccines, or proteins that could be used to treat human illnesses. For example, one company engineered corn to produce experimental vaccines for the Human Immunodeficiency Virus and the Hepatitis B virus, while another company engineered corn and sugarcane to produce cancer-fighting agents. These techniques are still experimental, and from 2001 to 2003 these four companies conducted limited field tests of these genetically engineered pharmaceutical-producing plant varieties ("GEPPVs") on Kauai, Maui, Molokai, and Oahu.

ProdiGene, Monsanto, HARC, and Garst Seed received permits to plant these crops from the United States Department of Agriculture, Animal and Plant Health Inspection Service ("APHIS"). The companies have already planted and harvested these crops, the permits have expired, and the companies are no longer planting crops pursuant to these permits.

The Plaintiffs argue that APHIS[1] broke the law in issuing these permits. Because these crops produce experimental pharmaceutical products, the Plaintiffs argue, their effect on Hawaii's ecosystem (especially Hawaii's 329 endangered and threatened species) is unclear. The Plaintiffs contend that these experimental crops could cross-pollinate with existing food crops, thus contaminating the food supply. The Plaintiffs also argue that animals that feed on corn (as well as animals further up the food chain that feed on corn-eating animals) would become unwitting carriers of experimental pharmaceutical products, causing even more widespread dissemination of these experimental vaccines, hormones, and proteins. According to the Plaintiffs, APHIS was required to evaluate the environmental impact of these genetically engineered crops before issuing the permits. In failing to do so, the Plaintiffs argue, APHIS violated both the National Environmental Policy Act ("NEPA") and the Endangered Species Act ("ESA").

APHIS, on the other hand, argues that it fulfilled its statutory obligations. APHIS contends that it placed strict conditions on the permits to ensure that the genetically modified crops would not contaminate the environment, such that it complied with both the ESA and NEPA. And according to APHIS,

[1] For ease of reference, the court will refer to the Defendants collectively as "APHIS" or "Defendants."

because the Plaintiffs have failed to demonstrate any environmental harm from these open air field tests, the Plaintiffs' claims necessarily fail.

After more than two and a half years of contentious litigation, the court heard the parties' motions for summary judgment on July 7, 2006. Based on the following, the court GRANTS IN PART and DENIES IN PART the Plaintiffs' motion for summary judgment and GRANTS IN PART and DENIES IN PART the Defendants' motion for summary judgment.[2] The court concludes that APHIS violated both the ESA and NEPA in issuing the four permits, and the court will hold a hearing on the appropriate remedies in this case on August 22, 2006.

In addition to the dispute over the four permits, there is a dispute over a petition for rulemaking submitted to APHIS by the Plaintiffs. The Plaintiffs submitted a Petition to APHIS on December 16, 2002 in which the Plaintiffs sought five specific actions from APHIS, and the Plaintiffs argue that APHIS arbitrarily and capriciously denied the Petition. The court concludes that the Defendants are entitled to summary judgment as to this claim.

[2] As discussed more fully *infra*, the court grants summary judgment in favor of the Plaintiffs as to Counts One, Two, Three, Four, Six, Seven, Eight, and Nine of the Plaintiffs' Second Amended Complaint; the court grants summary judgment in favor of the Defendants as to Count Eleven; and the court withholds ruling as to Counts Five and Ten.

II. BACKGROUND

A. Legal Framework

A brief description of the legal framework applicable to the instant case may assist in placing the facts in context. The Plaintiffs allege APHIS violated the ESA, NEPA, and the Plant Protection Act ("PPA"), and the court addresses each of these statutes, along with the Administrative Procedure Act ("APA"), in turn.

1. Endangered Species Act

One of the express policies of the Endangered Species Act, 16 U.S.C. § 1531 et seq., is to ensure "that all Federal departments and agencies shall seek to conserve endangered species and threatened species[.]" 16 U.S.C. § 1531(c)(1). The ESA mandates interagency collaboration, through a series of procedural requirements outlined in the statute, to effectuate Congress's goals of protecting endangered and threatened plant and animal species. 16 U.S.C. §§ 1532, 1536. Specifically, the ESA requires the following:

> [E]ach Federal agency shall . . . request of the Secretary [of the Interior] information whether any species which is listed or proposed to be listed [as an endangered species or a threatened species] may be present in the area of such proposed action. If the Secretary advises, based on the best scientific and commercial data available, that such species may be present, such agency shall conduct a biological assessment for the

> purpose of identifying any endangered species or threatened species which is likely to be affected by such action.

16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12(c) (requiring federal agencies to request information regarding listed species and critical habitat from the Department of the Interior). *See also* 16 U.S.C. § 1532(15) (defining "Secretary"); 16 U.S.C. § 1533 (setting forth guidelines for listing endangered and threatened species). In other words, whenever an agency is considering taking an "action,"[3] that agency must request a list, from either the United States Fish and Wildlife Service ("FWS") or the National Marine Fisheries Service ("NMFS"), of those endangered and threatened species present in the geographic area of the proposed action. As the Ninth Circuit recently explained:

> An agency's decision whether to take a discretionary action that may jeopardize endangered or threatened species is strictly governed by ESA-mandated inter-agency consultation procedures. First, the agency contemplating the action must request information from the appropriate federal wildlife service regarding "whether any species which is listed or proposed to be listed may be present in the area of such proposed action."

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[3] "Agency action" is defined in the ESA as "any action authorized, funded, or carried out by such agency[.]" 16 U.S.C. § 1536(a)(2). The joint regulations (promulgated by the United States Fish & Wildlife Service and the National Marine Fisheries Service) implementing the ESA similarly provide that "'Action' means all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas." 50 C.F.R. § 402.02. The instant case involves an agency's issuance of four permits, and APHIS does not dispute that the granting of these permits is "agency action" sufficient to trigger the requirements of the ESA.

Forest Guardians v. Johanns, 450 F.3d 455, 457 (9th Cir. 2006) (quoting 16 U.S.C. § 1536(c)(1)) (citations omitted).

The ESA and the regulations implementing the ESA, 50 C.F.R. Part 402, describe various processes ("informal consultation," "formal consultation," and "biological assessment") and the circumstances under which an agency must engage in each type of process. *See Forest Guardians*, 450 F.3d at 457 ("If [FWS] determines that listed species may be present in the affected area, the agency preparing to act must produce a 'biological assessment' in accordance with the [NEPA] . . . . If the biological assessment concludes that listed species are in fact likely to be adversely affected, the agency ordinarily must enter 'formal consultation' with [FWS].").

2. National Environmental Policy Act

The National Environmental Policy Act, 42 U.S.C. § 4321 et seq., states that "each person should enjoy a healthful environment and that each person has a responsibility to contribute to the preservation and enhancement of the environment." 42 U.S.C. § 4331(c). To that end, NEPA requires federal agencies to evaluate the impact of their actions on the natural environment. *See* 42 U.S.C. § 4332. Specifically, NEPA requires all federal agencies to "include in every recommendation or report on proposals for legislation and other major Federal

actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on . . . the environmental impact of the proposed action[.]" 42 U.S.C. § 4332(2)(c).

Through NEPA, Congress established the Council on Environmental Quality ("CEQ"), which has promulgated regulations requiring all agencies to comply with certain procedures before acting. 42 U.S.C. § 4342; 40 C.F.R. Part 1500. The CEQ regulations require agencies to prepare an "environmental assessment" ("EA") and/or an "environmental impact statement" ("EIS") before acting, except in limited circumstances. 40 C.F.R. §§ 1501.3, 1501.4. An EIS is "a detailed written statement as required by" NEPA, and an EA is "a concise public document" that an agency prepares when deciding whether it needs to prepare a more extensive EIS. 40 C.F.R. §§ 1508.9, 1508.11.

There are circumstances under which an agency may avoid preparing either an EA or an EIS. The CEQ regulations allow federal agencies to develop "categorical exclusion[s]" to the EA/EIS requirements for routine agency actions that are known to have no significant effect on the human environment:

> *Categorical exclusion* means a category of actions which do not individually or cumulatively have a significant effect on the human environment and which have been found to have no such effect . . . and for which, therefore, neither an environmental assessment nor an environmental impact statement is required. . . . Any procedures under this section

> shall provide for extraordinary circumstances in which a normally excluded action may have a significant environmental effect.

40 C.F.R. § 1508.4.

APHIS promulgated its own regulations to ensure that its actions complied with NEPA and with the CEQ regulations. In 7 C.F.R. § 372.5, APHIS describes four categories of actions: "Actions normally requiring environmental impact statements"; "Actions normally requiring environmental assessments but not necessarily environmental impact statements"; "Categorically excluded actions"; and "Exceptions for categorically excluded actions." (Italics omitted.) In other words, 7 C.F.R. § 372.5 generally tracks the CEQ's requirements (as set forth in 40 C.F.R. § 1508.4): It allows federal agencies to develop categorical exclusions, but requires agencies to "provide for extraordinary circumstances in which a normally excluded action may have a significant environmental effect."

The APHIS regulations regarding categorically excluded actions provide in relevant part:

> This class of APHIS actions shares many of the same characteristics . . . as the class of actions that normally requires environmental assessments but not necessarily environmental impact statements. The major difference is that the means through which adverse environmental impacts may be avoided or minimized have actually been built right into the actions themselves. The efficacy of this approach generally has been

> established through testing and/or monitoring. . . . [Types of categorically excluded actions] include:
>
> . . . .
>
> (3) *Licensing and permitting*. . . .
>
> (ii) Permitting, or acknowledgement of notifications for, confined field releases of genetically engineered organisms and products[.]

7 C.F.R. § 372.5(c). The relevant exception to this categorical exclusion appears in 7 C.F.R. § 372.5(d):

> Whenever the decisionmaker determines that a categorically excluded action may have the potential to affect "significantly" the quality of the "human environment," as those terms are defined at 40 CFR 1508.27 and 1508.14, respectively, an environmental assessment or an environmental impact statement will be prepared. For example:
>
> . . . .
>
> (4) When a confined field release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues.

In sum, APHIS does not need to prepare an EA or an EIS when it issues permits for actions in which "the means through which adverse environmental impacts may be avoided or minimized have actually been built right into the actions themselves" -- such as "confined field release[s] of genetically engineered organisms and products" -- so long as those field releases do not "involve[] new species or organisms or novel modifications that raise new issues."[4]

[4] Although there are other exceptions to the categorical exclusions, the court is focusing only on the sole exception that is relevant to the instant case.

In interpreting the statutes and regulations cited *supra*, the Ninth Circuit has held that, "[w]hen an agency decides to proceed with an action in the absence of an EA or EIS, the agency must adequately explain its decision." *Alaska Ctr. for the Env't v. U.S. Forest Serv.*, 189 F.3d 851, 859 (9th Cir. 1999). "NEPA's procedural requirements require agencies to take a 'hard look' at the environmental consequences of their actions. A hard look includes 'considering all foreseeable direct and indirect impacts.'" *Earth Island Inst. v. U.S. Forest Serv.*, 442 F.3d 1147, 1159 (9th Cir. 2006) (quoting *Idaho Sporting Cong. v. Rittenhouse*, 305 F.3d 957, 973 (9th Cir. 2002)). "'An agency cannot avoid its statutory responsibilities under NEPA merely by asserting that an activity it wishes to pursue will have an insignificant effect on the environment.'" *Alaska Ctr. for the Env't*, 189 F.3d at 859 (quoting *Jones v. Gordon*, 792 F.2d 821, 828 (9th Cir. 1986)). To comply with NEPA, "'[t]he agency must supply a convincing statement of reasons why potential effects are insignificant.'" *Id*. (quoting *Steamboaters v. Fed. Energy Regulatory Comm'n*, 759 F.2d 1382, 1393 (9th Cir. 1985)).

There does not appear to be any specific process an agency must follow in determining that a categorical exclusion applies and that an exception to that exclusion does not apply; the agency must simply explain its decision in a

reasoned manner. *Cal. v. Norton*, 311 F.3d 1162, 1176 (9th Cir. 2002) ("In many instances, a brief statement that a categorical exclusion is being invoked will suffice."); *Alaska Ctr. for the Env't*, 189 F.3d at 859 ("Once the agency considers the proper factors and makes a factual determination on whether the impacts are significant or not, that decision implicates substantial agency expertise and is entitled to deference.").

3. Plant Protection Act and Administrative Procedure Act

The Plant Protection Act ("PPA"), 7 U.S.C. § 7701 et seq., was enacted in 2000 to attempt to detect, control, eradicate, and suppress plant pests and noxious weeds. 7 U.S.C. § 7701(1). The PPA gives the Secretary of Agriculture the authority to promulgate regulations to prevent the introduction and dissemination of plant pests. 7 U.S.C. §§ 7702(16), 7711(a). The PPA regulations appear in 7 C.F.R. Part 340.

The Plaintiffs do not claim that APHIS violated the PPA. Instead, as discussed more fully *infra*, the Plaintiffs contend that they asked APHIS to promulgate rules pursuant to the PPA; that APHIS ignored the Plaintiffs' request; and that APHIS's inaction violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 et seq.

The APA allows for judicial review of agency actions. It provides in relevant part:

> The reviewing court shall–
>
> (1) compel agency action unlawfully withheld or unreasonably delayed; and
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be–
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
> (B) contrary to constitutional right, power, privilege, or immunity;
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or]
> (D) without observance of procedure required by law . . . .

5 U.S.C. § 706. As discussed *infra*, the Plaintiffs argue that APHIS violated the APA by refusing to act on their rulemaking request for the past three and a half years. As stated in *Environmental Defense Fund, Inc. v. Hardin*, 428 F.2d 1093, 1099 (D.C. Cir. 1970):

> [R]elief delayed is not always equivalent to relief denied. There are many factors that result in delay, and a court is in general ill-suited to review the order in which an agency conducts its business. But when administrative inaction has precisely the same impact on the rights of the parties as denial of relief, an agency cannot preclude judicial review by casting its decision in the form of inaction rather than in the form of an order denying relief.

(Footnote omitted.)

B. Factual Background

Between 2001 and 2003, ProdiGene, Monsanto, HARC, and Garst Seed submitted applications to APHIS to conduct field tests of GEPPVs in various locations in Hawaii. The administrative record indicates that APHIS reviewed each of the four permits pursuant to the PPA regulations contained in 7 C.F.R. Part 340 (regulating the introduction of genetically modified organisms which are or may be plant pests). For each permit application, APHIS sent a letter (at least two pages long in all four cases) to the State of Hawaii. These letters indicated that APHIS believed that the proposed field testing would not present any risk of plant pest introduction or dissemination; the letters also asked the State to comment on APHIS's findings and respond to APHIS within thirty days. Administrative Record ("AR") 50-52 (review of Prodigene's application); AR 151-53 (HARC); AR 297-99 (Garst Seed); AR 595-97 (Monsanto).

In its letters to the State, APHIS explained that some of the donor organisms used by the four companies in their field tests were "plant pests" as described in 7 C.F.R. Part 340. Nevertheless, APHIS approved the four permits, making specific findings as to each permit that the proposed field testing was "confined" or "controlled" and therefore in compliance with 7 C.F.R. § 340.4

("Permits for the introduction of a regulated article.").[5] AR 50 ("[W]e conclude that this is a confined release of the genetically engineered corn plants described in this application, and the test will not present any risk of plant pest introduction or dissemination for the reasons cited below[.]"); AR 151 ("[W]e conclude that this is a confined release of the genetically engineered sugarcane plants described in this application, and that the test will not present any risk of plant pest introduction or dissemination for the reasons cited below[.]"); AR 298 ("[W]e conclude that controlled field testing of the genetically engineered corn plants described in this application will not present any risk of plant pest introduction or dissemination for the reasons cited below[.]"); AR 596 ("[W]e conclude that controlled field testing of the genetically engineered corn plants described in this application will not present any risk of plant pest introduction or dissemination for the reasons cited below[.]"). These findings were specifically limited to the PPA. Nothing in the administrative record demonstrates that APHIS made any findings or conclusions

[5] The PPA regulations do not specifically use the words "confined" or "controlled," but the regulations require an applicant to include, *inter alia*, "[a] detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination[.]" 7 C.F.R. § 340.4(b)(10). The word "confined" is used in 7 C.F.R. § 372.5(c)(3)(ii) (the categorical exclusion in APHIS's NEPA regulations), but not in the PPA regulations.

specifically regarding categorical exclusions or exceptions to those exclusions for purposes of complying with NEPA.[6]

Similarly, nothing in the administrative record indicates that APHIS considered whether approval of the four permits would adversely affect endangered or threatened species or critical habitats. In fact, the only indication in the administrative record that anyone considered endangered species in relation to these four permits is a list of species provided by ProdiGene in an amendment to their permit application. AR 77.

On December 16, 2002, the Plaintiffs submitted a Petition on Genetically Engineered Pharmaceutical-Producing Plant Varieties ("Petition") to APHIS. Plaintiffs' Concise Statement of Material Facts in Support of Motion for Summary Judgment ("Plaintiffs' Concise"), Ex. 18. The Petition asked APHIS to do the following:

> 1. Promulgate New GEPPV Regulations. Publish draft and then final regulations that promulgate mandatory state-of-the-

[6] The PPA is more narrowly focused than NEPA: whereas the PPA targets "plant pests" and "noxious weeds," 7 U.S.C. § 7701(1), NEPA's goal is "preservation and enhancement of the environment." 42 U.S.C. § 4331(c). The limited finding that APHIS took the "hard look" required by the PPA (regarding the environmental consequences to *plants*), even under a highly deferential standard of review, does not satisfy the requirement that APHIS consider NEPA's broader environmental considerations. Thus, as discussed more fully *infra*, absent *anything* in the administrative record demonstrating that APHIS considered broader environmental concerns beyond the narrow issue of the spread of plant pests and noxious weeds, APHIS's action was arbitrary and capricious.

art protections, including broad prohibitions on the use of food crops as GEPPVs and prohibitions on the outdoor growing of GEPPVs in order to prevent unauthorized exposures and to prevent future contamination of the food supply and the environment by unwanted pharmaceutical and chemical compounds.

2. Undertake a Programmatic EIS for GEPPVs. Comply with the National Environmental Policy Act by preparing a Programmatic Environmental Impact Statement ("PEIS") assessing the impacts of alternative future approaches for APHIS's regulatory program on GEPPVs. The reasonable alternative approaches assessed should include, but not be limited to, regulatory prohibitions on the use of food crops as GEPPVs and on further outdoor planting of GEPPVs.

3. Change Existing [United States Department of Agriculture ("USDA")] CBI and FOIA Policies and Regulations. Change USDA and APHIS's policies and regulations on confidential business information ("CBI") and the Freedom of Information Act ("FOIA") to provide more prompt, comprehensive responses and to facilitate prompt disclosure of all relevant CBI when a party who has claimed the CBI protections violates APHIS's containment rules and causes an unauthorized exposure of any person, the grain or food supply, or the environment to a GEPPV.

4. Create a Publicly Available Field Test Violations Database. Maintain an updated list on the APHIS website of all containment violations for GEPPVs, including name of the violator; date of violation; precise location and extent of any contamination; specific identity of the GEPPV involved; response actions by APHIS, the violator, and other entities; and other pertinent information.

5. Institute an Immediate Moratorium on Certain Plantings. Institute an immediate moratorium on all use of food crops as GEPPVs, and all further outdoor planting of GEPPVs, to allow

> for the development of the requested regulations, the PEIS, and the improved public disclosure program. While these program improvements are pending APHIS should, with respect to any proposed uses of food crops as GEPPVs and proposed outdoor GEPPV plantings: (1) deny all notifications; (2) deny all applications for permits; and (3) deny all petitions for deregulated status.

Plaintiffs' Concise, Ex. 18 at 2-3.

On March 10, 2003, APHIS requested public comments on its permitting process for the field testing of plants genetically engineered to produce pharmaceutical and industrial compounds. AR 1527 (also available at 68 FR 11337-01). APHIS received over 6,000 comments from individuals and organizations opposed, to varying degrees, to the concept of field testing of GEPPVs. AR 1531-2441; *see also* AR 2442-64 (summary of public comments).

On April 17, 2003, APHIS sent the Plaintiffs a letter responding to the Plaintiffs' December 16, 2002 Petition. AR 3021-24. The Plaintiffs claim that this letter was not a "response" in that APHIS neither granted nor denied the Plaintiffs' requests; instead, according to the Plaintiffs, APHIS simply dismissed the Plaintiffs' concerns and have, to date, refused to act on the Plaintiffs' requests. The court requested supplemental briefing as to what, if anything, APHIS did in response to the Plaintiffs' Petition. In its supplemental brief, APHIS explained that it has done the following: (1) it published a notice of intent ("NOI") in the Federal

Register on January 23, 2004 to "prepare an [EIS] in connection with potential changes to the regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms"; (2) it has been working on a Draft EIS since publishing the NOI and this Draft EIS "is currently being reviewed both internally at the USDA as well as at other governmental agencies"; and (3) it has established several web pages dedicated to GEPPV permitting. 69 FR 3271; Declaration of John T. Turner, Ph.D. (attached to APHIS's Supplemental Brief). APHIS's Supplemental Brief also lists a number of reasons why APHIS believes its existing policies address the Plaintiffs' concerns, but the only concrete actions identified by APHIS's brief are the three items just mentioned. For example, as to Item 3 in the Plaintiffs' Petition (requesting that APHIS change existing CBI and FOIA policies), APHIS's April 17, 2003 letter stated that APHIS is legally required to protect CBI but that APHIS would make information available to the public for those containment violations that have "'potential environmental and health risks.'" AR 3023. APHIS does not identify any specific actions taken by APHIS with respect to the Plaintiffs' Item 3 since issuance of the April 2003 letter, however. Similarly, as to Item 4 in the Plaintiffs' Petition (requesting creation of a field test violations database), APHIS claims that it has established some websites containing permit information; APHIS does not

allege that it has taken any action with respect to a publicly available database of *all* field test *violations*, as requested by the Plaintiffs. As to Item 5 in the Plaintiffs' Petition (requesting an immediate moratorium), the April 17, 2003 letter stated that "[f]ield tests of GEPPVs have been conducted safely to date under conditions of confinement" but that "[a]n immediate moratorium on the use of food crops for GEPPVs and/or field testing of GEPPVs would be considered . . . should a series of unforeseen circumstances warrant such action[.]" AR 3023-24. In its Supplemental Brief, however, APHIS does not explain what (if anything) it has done since April 2003 with respect to Item 5 of the Plaintiffs' Petition.

C. Procedural Background

The Plaintiffs filed their Complaint in November 2003, and filed a First Amended Complaint in February 2004. Court Record ("CR") 1, 154. The Biotechnology Industry Organization ("BIO") -- a nonprofit trade association that represents over 1,100 biotechnology companies -- filed a motion to intervene in April 2004; Magistrate Judge Barry Kurren granted in part and denied in part BIO's request, ruling that BIO could intervene "with respect to discovery issues regarding information on BIO's members and issues of injunctive relief." CR 29, 63. United States District Court Judge David Alan Ezra affirmed the Magistrate Judge's ruling. CR 75. The Defendants filed several motions to dismiss, which

Judge Ezra denied in written orders dated January 26, 2005, March 2, 2005, and July 18, 2005. CR 117, 127, 151.

The Plaintiffs filed a Second Amended Complaint on August 1, 2005. CR 154. The Plaintiffs and the Defendants filed motions for summary judgment, and the court heard arguments on the motions on July 7, 2006.[7] On July 11, 2006,

[7] The Plaintiffs and BIO each filed a motion to strike in the weeks before the hearing on the parties' motions for summary judgment, and the court denied those motions without prejudice. These motions to strike related to the parties' use of extra-record evidence; the court denied the motions to strike, but informed the parties that it would consider the parties' concerns once the court had a better understanding of the facts of the case (and thus a better understanding of the context of the extra-record evidence).

As the Ninth Circuit has explained, "[j]udicial review of an agency decision typically focuses on the administrative record in existence at the time of the decision and does not encompass any part of the record that is made initially in the reviewing court." *Southwest Ctr. for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1450 (9th Cir. 1996). There are four situations in which extra-record evidence may be considered:

> (1) when the record need be expanded to explain agency action;
> (2) when the agency has relied upon documents or materials not included in the record;
> (3) to explain or clarify technical matter involved in the agency action and
> (4) where there has been a strong showing in support of a claim of bad faith or improper behavior on the part of the agency decision makers.

Cactus Corner, LLC v. U.S. Dept. of Agric., 346 F. Supp. 2d 1075, 1105 (E.D. Cal. 2004) (paraphrasing *Pub. Power Council v. Johnson*, 674 F.2d 791 (9th Cir. 1982)). *See also Southwest Ctr. for Biological Diversity*, 100 F.3d at 1450 ("Review may, however, be expanded beyond the record if necessary to explain agency decisions."). In reaching the conclusions set forth below, the court has not relied upon any of the extra-record evidence that was the subject of the parties' motions to strike. The court has, however, considered one piece of extra-record evidence submitted by one of the parties: the declaration of John T. Turner, Ph.D. (attached to APHIS's Supplemental Brief), which discusses APHIS's progress on the Programmatic EIS. The court finds that this extra-record declaration is necessary to explain APHIS's actions over the last three and a half years so as to allow the court to rule on APHIS's ripeness argument.

the court requested additional briefing from the parties as to Count Eleven of the Plaintiffs' Second Amended Complaint (the Plaintiffs' Plant Protection Act claim).

In its Second Amended Complaint, the Plaintiffs allege the following: (1) APHIS violated NEPA and the ESA in issuing each of the four permits at issue in this case (Counts One through Four and Six through Nine, respectively); (2) APHIS violated NEPA and the ESA in implementing its GEPPV program (Counts Five and Ten, respectively); and (3) APHIS violated the PPA and the APA in failing to respond to its Petition (Count Eleven). As discussed *infra*, the court concludes as follows: (1) APHIS violated the ESA and NEPA in issuing the four permits, such that the Plaintiffs are entitled to summary judgment on Counts One through Four and Six through Nine; (2) Counts Five and Ten appear to be claims for broad-based relief based on violations of the ESA and NEPA (as set forth in Counts One through Four and Six through Nine), such that the court withholds ruling on Counts Five and Ten; and (3) APHIS is entitled to summary judgment as to Count Eleven (the Plaintiffs' PPA claim), because APHIS's actions are either unripe for review or were justified in the administrative record (and therefore satisfy the arbitrary and capricious standard).

III. STANDARD OF REVIEW

Pursuant to the APA, the court reviews APHIS's actions to determine whether those actions were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 5 U.S.C. § 706(2)(A). As the Ninth Circuit has explained, "[a]n agency decision is arbitrary and capricious if the agency 'has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency.'" *Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv.*, 450 F.3d 930, 937 (9th Cir. 2006) (quoting *Pac. Coast Fed'n of Fishermen's Ass'ns, Inc. v. Nat'l Marine Fisheries Serv.*, 265 F.3d 1028, 1034 (9th Cir. 2001)) (alteration in original). *See also Alaska Ctr. for the Env't*, 189 F.3d at 858 n.5 ("The question of whether an action . . . fits within the categorical exclusion is a factual determination that implicates substantial agency expertise and is reviewed under the arbitrary and capricious standard.").

The focus of the Plaintiffs' Second Amended Complaint is on APHIS's alleged failure to comply with the procedures mandated in the ESA, NEPA, and APA. "Unlike substantive challenges, . . . our review of an agency's procedural compliance is exacting, yet limited." *Kern County Farm Bureau v.*

Allen, 450 F.3d 1072, 1076 (9th Cir. 2006). "The court must defer to an agency conclusion that is 'fully informed and well-considered,' but need not rubber stamp a 'clear error of judgment.'" *Anderson v. Evans*, 371 F.3d 475, 486 (9th Cir. 2004) (quoting *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir.1998)). Furthermore, as the Supreme Court explained in *Securities and Exchange Commission v. Chenery Corp.*, 332 U.S. 194, 196 (1947):

> [A] reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency. If those grounds are inadequate or improper, the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis. To do so would propel the court into the domain which Congress has set aside exclusively for the administrative agency.

IV. DISCUSSION

The court first examines the Plaintiffs' claims that issuance of the four permits violated the ESA;[8] the court grants summary judgment in favor of the Plaintiffs as to these claims. Second, the court discusses the Plaintiffs' claims that issuance of the four permits violated NEPA;[9] the court also grants summary judgment in favor of the Plaintiffs as to these claims. Third, the court addresses

[8] Counts Six, Seven, Eight, and Nine of the Plaintiffs' Second Amended Complaint.

[9] Counts One, Two, Three, and Four of the Plaintiffs' Second Amended Complaint.

the Plaintiffs' claims that APHIS's "GEPPV program" violated the ESA and NEPA;[10] as discussed *infra*, the Plaintiffs appear to be asking for broad-scale remedies based on the violations of the ESA and NEPA in issuing the four permits (rather than setting forth discrete claims for relief), such that the court will address these claims at the hearing on August 22. Finally, the court examines the Plaintiffs' claim that APHIS acted arbitrarily and capriciously in denying their December 16, 2002 Petition;[11] the court grants summary judgment in favor of the Defendants as to this claim.

A. Endangered Species Act

Hawaii is known not only for its remarkable landscape and beaches, but also for its considerable number of endangered and threatened species. The Fish and Wildlife Service reports on its website that there are 329 endangered and threatened plant and animal species in Hawaii, including thirty-two types of birds.[12] Hawaii has more endangered and threatened species than any other state, and Hawaii's 329 listed species represent approximately twenty-five percent of all

[10] Counts Ten and Five, respectively, of the Plaintiffs' Second Amended Complaint.

[11] Count Eleven of the Plaintiffs' Second Amended Complaint.

[12] *See* FWS Threatened and Endangered Species System ("TESS"), http://ecos.fws.gov/tess_public/StateListing.do?state=HI&status=listed (listing 273 plants and 56 animals in Hawaii as endangered or threatened); FWS, Pacific Islands -- Endangered Species, http://www.fws.gov/pacificislands/wesa/endspindex.html#Hawaiian (describing Hawaii's endangered species).

listed species in the United States.[13] Although strict compliance with the ESA's procedural requirements is always critically important, these requirements are particularly crucial in Hawaii given Hawaii's extensive number of threatened and endangered species.

As discussed *supra*, 16 U.S.C. § 1536(c)(1) requires all agencies -- including APHIS -- to obtain information from FWS and NMFS about any "listed" species in the geographic area of the proposed agency action. This initial request for information is a predicate to further agency action and may not be ignored, regardless of whatever other processes the agency follows. *See Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985) (holding that ESA's "procedural requirements are designed to ensure compliance with the substantive provisions").

APHIS argues that it complied with the ESA in issuing the four permits. APHIS points to 50 C.F.R. § 402.14, which provides that "[e]ach Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat"; APHIS argues that it determined that its proposed actions would not affect listed species or critical habitat, such that formal consultation was not required.

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[13] *See* FWS TESS, http://ecos.fws.gov/tess_public/StateListing.do?state=all. Hawaii has 329 threatened and endangered plant and animal species out of a total of 1,310 in the United States. *See* FWS TESS, http://ecos.fws.gov/tess_public/Boxscore.do.

APHIS's argument misses the mark. The problem is not with APHIS's decision not to conduct a formal consultation: APHIS may ultimately be correct that formal consultation was not required (though the court makes no findings on this point), but this is not the real issue. Instead, the problem is that APHIS skipped the initial, mandatory step of obtaining information about listed species and critical habitats from FWS and NMFS.

At the July 7, 2006 hearing, the court questioned APHIS's counsel directly and repeatedly as to whether the initial step outlined in § 1536(c)(1) (obtaining information about listed species from FWS) was required and, if so, whether APHIS complied with this procedural requirement. APHIS's counsel did not answer these questions. Instead, counsel simply reiterated that "formal consultation" was not required, ignoring the court's questions about the pre-consultation, information-gathering procedure required by the ESA.

Regardless of whether the field tests of the genetically modified crops were "confined" (as discussed more fully *infra*), and regardless of whether APHIS's actions were in fact innocuous with respect to listed species and habitats, APHIS violated the ESA. APHIS engaged in "agency action" -- granting a series of permits to field test genetically modified crops -- without fulfilling its congressionally mandated duty to obtain information from FWS and NMFS

regarding endangered species, threatened species, and critical habitats. Even if APHIS is ultimately correct in its assertion that no listed species or habitats have been harmed, APHIS's actions are nevertheless tainted because APHIS failed to comply with a fundamental procedural requirement. APHIS's utter disregard for this simple investigation requirement, especially given the extraordinary number of endangered and threatened plants and animals in Hawaii, constitutes an unequivocal violation of a clear congressional mandate.

In an apparent effort to mitigate, APHIS turns to its second argument: "No harm, no foul." APHIS argues that, because the Plaintiffs have not provided any evidence to show that a single listed species or habitat was harmed in any way, the Plaintiffs' claims necessarily fail. This argument is absurd. An agency violates the ESA when it fails to follow the procedures mandated by Congress, and an agency will not escape scrutiny based on the fortunate outcome that no listed plant, animal, or habitat was harmed. APHIS's argument essentially asks the court to believe that APHIS is immune from suit, no matter how egregious the violation of the ESA, so long as APHIS does not cause any substantive harm to any listed species or habitat. In other words, APHIS argues that the Plaintiffs may not proceed with a lawsuit against the agency unless APHIS actually facilitates an organism's extinction. This after-the-fact justification (and good fortune) cannot

absolve APHIS of its failure to follow a clear congressional mandate. *See, e.g.*, *Wash. Toxics Coal. v. Envtl. Prot. Agency*, 413 F.3d 1024, 1035 (9th Cir. 2005) ("'It is not the responsibility of the plaintiffs to prove, nor the function of the courts to judge, the effect of a proposed action on an endangered species when proper procedures have not been followed.'" (Quoting *Thomas*, 753 F.2d at 765. 1985).)). As the Ninth Circuit has explained:

> The ESA's procedural requirements call for a systematic determination of the effects of a federal project on endangered species. If a project is allowed to proceed without substantial compliance with those procedural requirements, there can be no assurance that a violation of the ESA's substantive provisions will not result. The latter, of course, is impermissible.

Thomas, 753 F.2d at 764. In sum, the Defendants' argument is utterly without merit. The court therefore grants summary judgment in favor of the Plaintiffs as to Counts Six, Seven, Eight, and Nine of the Second Amended Complaint.

B. National Environmental Policy Act

The court concludes that APHIS violated NEPA because it failed to articulate its reasons for declining to prepare an EA or EIS. There is nothing in the administrative record to indicate that, contemporaneously with the issuance of the four permits, APHIS considered the applicability of NEPA, categorical exclusions, or the exceptions to those exclusions. In other words, APHIS failed to provide a reasoned explanation for its apparent determinations that a categorical exclusion

applied and that the exceptions to the exclusion did not apply. Consequently, APHIS's actions -- granting the four permits -- were arbitrary and capricious.

1. APHIS cannot rely on a categorical exclusion post hoc

The court could find nothing in the administrative record to indicate that APHIS considered NEPA when deciding whether to issue the four permits. Nowhere in the administrative record does APHIS discuss the applicability of the categorical exclusion or the exceptions to that exclusion. As the Ninth Circuit has explained:

> It is difficult for a reviewing court to determine if the application of an exclusion is arbitrary and capricious where there is no contemporaneous documentation to show that the agency considered the environmental consequences of its action and decided to apply a categorical exclusion to the facts of a particular decision. Post hoc invocation of a categorical exclusion does not provide assurance that the agency actually considered the environmental effects of its action before the decision was made.

Cal. v. Norton, 311 F.3d 1162, 1176 (9th Cir. 2002). At a bare minimum, an agency must state -- at the time it engages in the action in question (and not just when engaged in subsequent litigation) -- that it is invoking a categorical exclusion. *See id.* ("In many instances, a brief statement that a categorical exclusion is being invoked will suffice."). The court has no doubt that the members of APHIS's staff are, in fact, quite familiar with NEPA's requirements;

nevertheless, the court must review the administrative record, and the record itself is devoid of any consideration of the environmental consequences of APHIS's actions.

Although APHIS did not explicitly reference NEPA in the administrative record, there is evidence indicating that APHIS believed the permits involved "confined" field tests and that the categorical exclusion in 7 C.F.R. § 372.5(c)(3)(ii) ("[p]ermitting . . . confined field releases of genetically engineered organisms") applied. As discussed *supra*, the administrative record contains four letters (one for each of the four permits) from APHIS to the State of Hawaii indicating that APHIS believed these field tests were "confined" within the meaning of the PPA. APHIS argues that a categorical exclusion applied (that is, APHIS argues that it was not required to prepare an EA or an EIS because issuance of the four permits fell within a categorical exclusion -- because "the means through which adverse environmental impacts may be avoided or minimized have actually been built right into the [agency] actions themselves" -- specifically, because the four permits involved "confined field releases of genetically engineered organisms[.]" 7 C.F.R. §§ 372(c), 372(c)(3)(ii). In other words, APHIS argues that the four permits fit within its broad categorical exclusion in 7 C.F.R. § 372.5(c) (environmental mitigation measures built into the agency action

itself) and its own more specific categorical exclusion in 7 C.F.R. § 372.5(c)(3)(ii) ("confined field releases of genetically engineered organisms").

Given that APHIS's regulations allow for a categorical exclusion for "[p]ermitting, or acknowledgement of notifications for, confined field releases of genetically engineered organisms and products," 7 C.F.R. § 372.5(c)(3)(ii), and given that APHIS made a clear determination as to each permit application that the proposed field test was "confined" or "controlled," this court would have been satisfied had APHIS explained itself in any reasonable fashion as to the applicability of this categorical exclusion. *See Alaska Ctr. for the Env't v. U.S. Forest Serv.*, 189 F.3d 851, 857 (9th Cir. 1999) ("[A]n agency's interpretation of the meaning of its own categorical exclusion should be given controlling weight unless plainly erroneous or inconsistent with the terms used in the regulation."). APHIS cannot, however, abdicate its responsibilities during the administrative process and expect the court to defer to the agency's post hoc explanations. *See Cal. v. Norton*, 311 F.3d at 1176 ("Post hoc invocation of a categorical exclusion does not provide assurance that the agency actually considered the environmental effects of its action before the decision was made."). Furthermore, the fact that a field test is "confined" or "controlled" for purposes of the PPA does not necessarily mean that the field test is "confined" within the meaning of the

categorical exclusion within APHIS's NEPA regulations. While there may be substantial or complete overlap between 7 C.F.R. Part 340 and 7 C.F.R. § 372.5(c)(3)(ii), there must be some indication in the administrative record that APHIS considered the environmental consequences of its actions. NEPA requires no less.

APHIS's effort to justify its actions falls short. APHIS points to a footnote in *Alaska Center for the Environment* for the proposition that an agency may explain its rationale for applying a categorical exclusion post hoc. Simply put, *Alaska Center* does not say what the Defendants think it does.[14] The Defendants also rely on *Cactus Corner, LLC v. U.S. Department of Agriculture*, 346 F. Supp. 2d 1075, 1122 (E.D. Cal. 2004), for the same notion (that an agency

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[14] The Defendants cite the following footnote from *Alaska Center for the Environment*:

> ACE also contends that the Forest Service is avoiding NEPA review by breaking proposed actions down into one-year temporary actions so as to fit within the categorical exclusion and not complete an EA. The question of whether an action is temporary and fits within the categorical exclusion is a factual determination that implicates substantial agency expertise and is reviewed under the arbitrary and capricious standard. [*Greenpeace Action v. Franklin*, 14 F.3d 1324 (9th Cir. 1992).] The Forest Service's categorization of one-year helicopter permits as temporary is not unreasonable or does not rise to the level of arbitrary and capricious.

Alaska Ctr. for the Env't, 189 F.3d at 858 n.5. The court disagrees with the Defendants that this footnote somehow eviscerates established Ninth Circuit law, discussed *supra*, that post hoc rationalizations are insufficient to survive the arbitrary and capricious standard.

need not explain its decision to apply a categorical exclusion). The facts of *Cactus Corner* are distinguishable from those in the instant case, however. In *Cactus Corner*, the court recognized that "'[p]ost hoc invocation of a categorical exclusion does not provide assurance that the agency actually considered the environmental effects of its action before the decision was made.'" *Id.* at 1122 (quoting *Cal. v. Norton*, 311 F.3d 1162, 1176 (9th Cir. 2002)). The court then explained:

> Here, by contrast, the nature and purpose of the [APHIS] Rule itself [regarding the importation of clementines], aimed at the prevention of Medfly introduction into the United States, is designed to protect human health and the environment. Its risk analyses adequately address all issues of environmental concern, particularly the threat of the spread of Medflies, the risk to plant life (crops), and the risk to consumers who could encounter larvae in a fruit. Any additional study as to the environmental impact of Medfly introduction would be repetitive of the agency's 2001 Environmental Assessment and resulting statement.

Id. APHIS does not argue that the "nature and purpose" of the four permits at issue in the instant case was to "protect human health and the environment." Furthermore, there is nothing to suggest that additional study or analysis by APHIS would have been repetitive or redundant in this case. APHIS simply did not do the type of analysis required by NEPA.

The court is mindful of the Supreme Court's mandate that, "[e]ven when an agency explains its decision with 'less than ideal clarity,' a reviewing

court will not upset the decision on that account 'if the agency's path may reasonably be discerned.'" *Alaska Dep't of Envtl. Conservation v. Envtl. Prot. Agency*, 540 U.S. 461, 497 (2004) (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)). To accept APHIS's argument in the instant case, however, the court either must guess at what APHIS meant or must accept APHIS's post hoc rationalization. Neither of these alternatives is acceptable.[15]

Based on the administrative record, the court concludes that APHIS's issuance of the four permits -- without an EA, an EIS, or an explanation as to why neither an EA nor an EIS was required -- was arbitrary and capricious. Furthermore, as explained in the following section, APHIS's issuance of the four permits without considering the exceptions to the applicable categorical exclusion was also arbitrary and capricious.

[15] APHIS also argued that it should be held to a lower standard because this was "informal" rather than "formal" agency action. This argument is similarly without merit. The court agrees with APHIS that no formal NEPA document was required and that, as a general rule, an agency action will survive the arbitrary and capricious standard even if the agency was disorganized in performing its review. Nevertheless, an agency action will not survive judicial review where the administrative record fails to reflect any consideration of environmental harm as required by NEPA.

2. APHIS's failure to consider the exceptions to the categorical exclusion renders APHIS's actions arbitrary and capricious

The categorical exclusion outlined in 7 C.F.R. § 372.5(c)(3)(ii), discussed *supra*, is subject to the exceptions outlined in 7 C.F.R. § 372.5(d), including the requirement that an EA or EIS must be prepared "[w]hen a confined field release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues." The Plaintiffs argue that this exception applies to the four permits at issue, such that APHIS violated NEPA by failing to prepare an EA or EIS.

As the Ninth Circuit has explained, "[w]here there is substantial evidence in the record that exceptions to the categorical exclusion may apply, the agency must at the very least explain why the action does not fall within one of the exceptions." *Cal. v. Norton*, 311 F.3d at 1177. In the instant case, whether the exception in 7 C.F.R. § 372(d)(4) *does* apply is unclear, but there is substantial evidence that it *may* apply. Applications and correspondence submitted by two of the four permittees state that the proposed field tests involve "novel" proteins. AR 11-17, 23-29, 42-43 (ProdiGene application repeatedly stating that the molecular biology of various plants had been altered so as to "[e]xpress[] a novel protein"); AR 600 (Monsanto memorandum to APHIS stating that "[t]he information enclosed with this document is in support of our request to amend the previously

approved application . . . for environmental release of transgenic corn containing vectors for novel proteins"); AR 699 (Monsanto memorandum discussing application for "particular genes of interest . . . categorized as novel proteins"). Whether the remaining two permit applications involve "novel modifications" that "raise new issues" is unclear. While the idea of genetically modifying food crops to produce experimental pharmaceutical products may certainly appear "novel" to a layperson, this court lacks the expertise to make this kind of determination. Whether the proposed field tests involve "novel modifications," and whether these modifications "raise new issues," are questions best left to APHIS; the court will defer to APHIS's judgment on these issues, but APHIS must articulate a reasoned decision based on the information available to it. *See High Sierra Hikers Ass'n v. Blackwell*, 390 F.3d 630, 639 (9th Cir. 2004) ("NEPA is a procedural statute that does not 'mandate particular results, but simply provides the necessary process to ensure that federal agencies take a hard look at the environmental consequences of their actions.'"(Quoting *Neighbors of Cuddy Mountain v. Alexander*, 303 F.3d 1059, 1070 (9th Cir. 2002).)).

In the instant case, APHIS has simply failed to provide *any* explanation for its implied determination that the exceptions to the categorical exclusion do not apply. This is not the type of reasoned decision-making required

of federal agencies, and it cannot stand. The court finds that there is substantial evidence that an exception to the categorical exclusion *may* apply and that APHIS was required to provide *some* explanation as to why, in its view, the exceptions did not apply. Consequently, the court concludes that APHIS's issuance of the four permits, without considering the exceptions to the categorical exclusions, was arbitrary and capricious. Therefore, the court grants summary judgment in favor of the Plaintiffs as to Counts One, Two, Three, and Four of the Second Amended Complaint.

C. The "GEPPV Program"

In Count Five of their Second Amended Complaint, the Plaintiffs argue that APHIS has a "GEPPV program" -- internal policies by which it issues permits and engages in other agency action -- and that APHIS violated NEPA in developing and implementing this program. Plaintiffs' Motion for Summary Judgment at 12-13; Second Amended Complaint at 29, 36. Similarly, in Count Ten of their Second Amended Complaint, the Plaintiffs argue that APHIS violated the ESA in developing and implementing its GEPPV program. Plaintiffs' Motion for Summary Judgment at 38; Second Amended Complaint at 33-34, 37.

Neither the Plaintiffs nor the Defendants have clearly articulated their arguments with respect to these claims. Whether there is, in fact, a "GEPPV

program" is not evident from the administrative record; whether APHIS complied with NEPA and the ESA in developing and implementing this alleged GEPPV program is similarly uncertain.

Given the parties' arguments in their briefs and at oral argument, Counts Five and Ten appear to be nothing more than requests for broad-based relief based on the ESA and NEPA violations articulated in Counts One through Four and Six through Nine (the NEPA and ESA violations for each of the four permits). Therefore, to the extent that Counts Five and Ten request injunctive relief for APHIS's *specific* violations of NEPA and the ESA (as alleged in Counts One through Four and Six through Nine), the court will hear Plaintiffs' arguments at the hearing on August 22, 2006.[16]

D. Plant Protection Act

In Count Eleven of their Second Amended Complaint, the Plaintiffs contend that APHIS has essentially denied their December 16, 2002 Petition, and that this effective denial was arbitrary and capricious. The Defendants argue that APHIS never denied the Petition, such that the Plaintiffs' claims are unripe. The

[16] If the court is mistaken, and the Plaintiffs were, in fact, attempting to set forth distinct and independent claims for relief in Counts Five and Ten, the Plaintiffs and the Defendants should address these issues in their supplemental briefs (due August 17, 2006). In other words, if either the Plaintiffs or the Defendants are seeking summary judgment as to Counts Five and/or Ten, their supplemental briefs should set forth their respective arguments.

Plaintiffs' Petition raises five issues, and the court will address each of these five issues in turn. The court concludes that Items 1 and 2 of the Plaintiffs' Petition ("Promulgate New GEPPV Regulations" and "Undertake a Programmatic EIS for GEPPVS") are unripe, and the court grants summary judgment in favor of the Defendants as to these issues. The court finds that Items 3, 4, and 5 of the Plaintiffs' Petition ("Change Existing USDA CBI and FOIA Policies and Regulations," "Create a Publicly Available Field Test Violations Database," and "Institute an Immediate Moratorium on Certain Plantings") were denied by APHIS. Nevertheless, the court concludes that these denials were neither arbitrary nor capricious. Therefore, the court grants summary judgment in favor of the Defendants as to Items 3, 4, and 5.

1. Items 1 and 2 of the Plaintiffs' Petition

APHIS has submitted evidence indicating that it is conducting the Programmatic EIS requested by the Plaintiffs in Item 2 of their Petition,[17] such that the Plaintiffs' claim is not yet ripe for review. As the Supreme Court has explained:

[17] The court begins by examining Item 2 of the Plaintiffs' Petition, inasmuch as the analysis of Item 1 flows naturally from the disposition of Item 2.

> [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." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-149, 87 S.Ct. 1507, 1515, 18 L.Ed.2d 681 (1967).
>
> In deciding whether an agency's decision is, or is not, ripe for judicial review, the Court has examined both the "fitness of the issues for judicial decision" and the "hardship to the parties of withholding court consideration." *Id.*, at 149, 87 S.Ct., at 1515. To do so in this case, we must consider: (1) whether delayed review would cause hardship to the plaintiffs; (2) whether judicial intervention would inappropriately interfere with further administrative action; and (3) whether the courts would benefit from further factual development of the issues presented.

Ohio Forestry Ass'n, Inc. v. Sierra Club, 523 U.S. 726, 732-33 (1998). *See also Nat'l Audubon Soc'y, Inc. v. Davis*, 307 F.3d 835, 850 (9th Cir. 2002) ("[W]e must determine whether the claims are prudentially ripe, based on two factors: (1) whether the issues are fit for judicial resolution and (2) the potential hardship to the parties if judicial resolution is postponed."). In the instant case, the second and third *Ohio Forestry* factors weigh strongly in APHIS's favor: judicial intervention would inappropriately interfere with APHIS's administrative proceedings, and the court would benefit from further factual development of the issues (specifically,

completion of the Programmatic EIS). Although the court recognizes that this ruling will cause some hardship to the Plaintiffs, insofar as APHIS continues to issue permits for field testing of GEPPVs, the court concludes that, taken together, the balance of factors favors APHIS.[18]

Although the Plaintiffs are understandably upset by the fact that this process has taken over three years, the court accepts APHIS's representations regarding the justification for the delay: scientific research and analysis, along with inter-agency discussions and negotiations, have simply taken a long time (despite APHIS's diligent efforts to move the process along). The court does not mean to suggest that a three-year delay in preparing an EIS is presumptively valid, nor does the court mean to suggest that APHIS may wait indefinitely. At the moment, however, the court concludes that the Plaintiffs' claim with respect to

[18] In July 2005, the Defendants argued that Count Eleven of the Plaintiffs' Amended Complaint should be dismissed because it was unripe, and Judge Ezra rejected the Defendants' ripeness argument. CR 151. Judge Ezra's Order stated that the "Defendants' alleged delay would amount to a denial of Plaintiffs' request for a promulgation of regulations" and that the Plaintiffs' allegations, "if taken as true as required on a motion to dismiss," would entitle the Plaintiffs to relief. CR 151. The standard of review of a motion for summary judgment (under Rule 56) is different than the standard of review of a motion to dismiss (under Rule 12), however; the parties have had additional time for discovery and analysis, and the fact that the court now grants the Defendants' motion for summary judgment on ripeness grounds is in no way inconsistent with Judge Ezra's order denying the Defendants' motion to dismiss on ripeness grounds.

Item 2 is unripe and therefore grants summary judgment in favor of the Defendants as to this issue.[19]

The court concludes that the Plaintiffs' claim with respect to Item 1 of their Petition is similarly unripe. APHIS stated in its April 17, 2003 letter that "[y]our request for the promulgation of new GEPPV regulations, including prohibitions on the use of food crops and outdoor growing of GEPPVs[,] represent one possibility which will be considered, if indicated by the resulting potential for public health and environmental harm[.]" AR 3022. Thus, according to APHIS, whether to promulgate new GEPPV regulations depends on the result of the Programmatic EIS, which is underway. Consequently, the court concludes that the Plaintiffs' claim is unripe and grants summary judgment in favor of the Defendants.

2. Items 3, 4, and 5 of the Plaintiffs' Petition

a. *APHIS denied Items 3, 4, and 5*

APHIS argues that the Plaintiffs' requests outlined in Items 3, 4, and 5 ("Change Existing USDA CBI and FOIA Policies and Regulations," "Create a Publicly Available Field Test Violations Database," and "Institute an Immediate

[19] Of course, if APHIS has in any way misrepresented the diligence with which APHIS is conducting this programmatic EIS or the rulemaking process, the Plaintiffs may reassert their claim in a new action.

Moratorium on Certain Plantings") have not been denied. APHIS's Supplemental Brief at 11. The court disagrees. In its April 17, 2003 letter, and again in its Supplemental Brief, APHIS claims that the actions requested in Items 3, 4, and 5 were and are unnecessary because the existing policies and procedures are sufficient, although APHIS leaves open the possibility that it would consider changing its regulations in the future if conditions were to change. There is nothing in the letter to indicate that APHIS intended to act on the Plaintiffs' requests, and there is no evidence that APHIS has acted on the Plaintiffs' requests in the last three and a half years.

With respect to Item 3 (CBI/FOIA), APHIS's April 17, 2003 letter states that APHIS is constrained by existing law but that APHIS would continue to work diligently to make as much information available to the public as possible. Although APHIS's April 17, 2003 letter did not clearly state that APHIS was denying the Plaintiffs' request, the letter effectively denied the Plaintiffs' requests. Essentially, APHIS's response was "not now, but maybe later." APHIS did not indicate an unequivocal intent to engage in certain actions; instead, APHIS stated that it *might* do something in the future should the right conditions arise. APHIS's statements that it would keep an open mind in the future do not negate these denials. Furthermore, in its Supplemental Brief, APHIS does not provide any

evidence of any agency activity as to Item 3. In short, APHIS denied the Plaintiffs' request on April 17, 2003.

> With respect to Item 4, the April 17, 2003 letter stated:
>
> > APHIS is in the process of upgrading the software and hardware used in tracking both inspections and violations under the provisions of 7 CFR Part 340. Our first priority for this revised, inclusive database is to aid in the day to day implementation of the regulations and to ensure compliance. However, we are also in the process of developing an adjunct database which could include the results of compliance inspections and investigations after facts have been verified and any penalties levied. With regard to the need to immediately inform the public about a violation involving GEPPVs, prompt disclosure requires the use of the press release as the most effective means for immediate dissemination of information to the press and the public.

AR 3023. In its Supplemental Brief, APHIS does not indicate whether this "adjunct database" was ever implemented; the Supplemental Brief simply states that APHIS has several websites with permit information. John T. Turner, Ph.D., who submitted a Declaration (attached to APHIS's Supplemental Brief), states that APHIS "has vastly enhanced the types and quantity of information readily accessible to the public on GEPPV permitting" and that "[s]erious compliance infractions are referred to APHIS' Investigative and Enforcement Services (IES) for thorough investigation." Declaration of John T. Turner, Ph.D. at ¶¶14, 18. The Plaintiffs' Petition, however, requested a means by which information on "*all*

containment violations for GEPPVs" would be available to the public. Plaintiffs' Concise, Ex. 18 at 2 (emphasis added). APHIS has not created this database and has not given any indication that it is in the process of creating this database. As such, APHIS denied Item 4 of the Plaintiffs' Petition.

With respect to Item 5 (moratorium), APHIS's April 17, 2003 letter states that "[f]ield tests of GEPPVs have been conducted safely to date under conditions of confinement[.]" AR 3023. The letter suggests that APHIS will consider new information as it arrives, but APHIS gives no indication that it intends to issue an immediate moratorium as to all GEPPV field testing. Indeed, according to the Plaintiffs, APHIS has issued thirty-eight permits since the Plaintiffs submitted their Petition (including one permit -- the Garst Seed permit discussed *supra* -- in Hawaii). Plaintiffs' Supplemental Brief at 4; Exhibit 1 to Plaintiffs' Supplemental Brief. *See also* AR 2928 (internal APHIS e-mail from March 6, 2003 stating that, "[w]ith regard to the CFS request for a moratorium on the use of GEPPVs, release of Monday's notice [the March 10, 2003 request for public comments] will be an indirect rejection of this request, as you are well aware"). Again, the court concludes that APHIS denied the Plaintiffs' request.

b. *APHIS's denials were not arbitrary or capricious*

APHIS then argues that even if its responses could be considered denials, APHIS's decisions were neither arbitrary nor capricious.[20] The court agrees.

With respect to Item 3, APHIS stated in its April 17, 2003 letter the following: (1) "APHIS has long encouraged the [agricultural biotechnology] industry to keep [CBI] claims to a minimum, and we have consistently required that verifiable justification for such claims be provided in writing"; (2) "our ongoing review of the APHIS regulatory program for biotechnology products includes an examination of the options open to us for ensuring that more detailed information is available to our State cooperators and the interested public"; (3) "we do not agree that disclosure of CBI under [FOIA] is simply a matter of agency discretionary policy . . . [because, under FOIA,] legitimately claimed and substantiated CBI claims are exempt from disclosure"; and (4) "[i]n any potential case . . . in which a containment violation occurred which involved 'potential environmental and human health risks,' APHIS and FDA officials would ensure that all data and information relevant to the prevention of such risks was made

[20] APHIS's Supplemental Brief argues that, assuming *arguendo* that Items 3 and 5 have been denied, those denials did not represent an abuse of APHIS's discretion. APHIS does not raise the possibility that Item 4 may have been denied but that the denial was reasonable; nevertheless, the court concludes that Item 4 was denied but that the denial was reasonable.

available to investigators . . . [and] to the public." AR 3022-23. Thus, APHIS offered a reasoned explanation for why it was not changing its policies: it was constrained by existing law (FOIA) and its existing policies were sufficient. Although the Plaintiffs' Petition provides legitimate reasons for why APHIS should have different policies relating to CBI, the Plaintiffs have not explained why APHIS's decision to the contrary -- based on equally legitimate concerns -- was arbitrary or capricious. *See Earth Island Inst. v. U.S. Forest Serv.*, 442 F.3d 1147, 1157 (9th Cir. 2006) ("We reverse under the arbitrary and capricious standard only if the agency has relied on factors that Congress has not intended it to consider, has entirely failed to consider an important aspect of the problem, or has offered an explanation for that 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."). Therefore, the court will not overturn APHIS's decision.

With respect to Item 4, although APHIS has not acted on the Plaintiffs' request, the court does not have the authority to order APHIS to act on this request. The Plaintiffs have not pointed to any statute or regulation that requires APHIS to establish a field test violations database, and as the Supreme Court explained in *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 64

(2004), "a claim under § 706(1)[21] can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*." While the Plaintiffs may set forth many valid reasons for why APHIS *should* create and maintain a field test violations database, the Plaintiffs have not pointed to any statute, regulation, or case that requires APHIS to do so. Consequently, APHIS's denial as to Item 4 was neither arbitrary nor capricious, such that the Defendants are entitled to summary judgment as to this issue.

With respect to Item 5, the Plaintiffs argued in their Petition that an immediate moratorium on field testing of GEPPVs was warranted because field testing of GEPPVs could cause harm to human health and/or the environment at large. In its April 17, 2003 letter, APHIS stated: (1) "Field tests of GEPPVs have been conducted safely to date under conditions of confinement, and APHIS has consistently strengthened existing safeguards when indicated by inspections and monitoring"; and (2) "[a]n immediate moratorium on the use of food crops for GEPPVs and/or field testing of GEPPVs would be considered . . . should a series of unforeseen circumstances warrant such action[.]" AR 3023-24. The Plaintiffs

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[21] 5 U.S.C. § 706(1), part of the Administrative Procedure Act, provides that a reviewing court shall "compel agency action unlawfully withheld or unreasonably delayed[.]" In *Southern Utah Wilderness Alliance*, the Supreme Court interpreted this statutory language to mean that a court cannot force an agency to take an action unless that action is required by law. *S. Utah Wilderness Alliance*, 542 U.S. at 63 ("[T]he only agency action that can be compelled under the APA is action legally *required*.").

are correct that an agency's conclusory statement generally will not constitute "reasoned decisionmaking" sufficient to survive arbitrary and capricious review. *See Am. Horse Prot. Ass'n, Inc. v. Lyng*, 812 F.2d 1, 6 (D.C. Cir. 1987) ("The two conclusory sentences quoted above are insufficient to assure a reviewing court that the agency's refusal to act was the product of reasoned decisionmaking."). Nevertheless, in the instant case, APHIS's explanations in its April 17, 2003 letter were enough to satisfy this standard. In April 2003, APHIS had regulations in place governing open-air field testing of GEPPVs; in responding to the Plaintiffs' Petition, APHIS concluded that an immediate moratorium was unnecessary because existing confinement measures were adequate. Although there is certainly evidence to support the Plaintiffs' position, there is insufficient evidence to demonstrate that APHIS acted arbitrarily or capriciously in continuing to follow its existing regulations (rather than refusing to consider any future permit applications). Furthermore, given that APHIS was (and is) producing a programmatic EIS and was (and is) considering changes to its regulations as a result, the decision to wait for the results of the EIS -- rather than impose an immediate moratorium -- seems quite reasonable. In short, APHIS's decision to deny Item 5 was neither arbitrary and capricious, and the Defendants are entitled to summary judgment as to this issue.

V. CONCLUSION

Based on the foregoing, the court GRANTS IN PART and DENIES IN PART the Plaintiffs' Motion for Summary Judgment and GRANTS IN PART and DENIES IN PART the Defendants' Motion for Summary Judgment: the court GRANTS summary judgment in favor of the Plaintiffs as to Counts One, Two, Three, Four, Six, Seven, Eight, and Nine of their Second Amended Complaint; the court GRANTS summary judgment in favor of the Defendants as to Count Eleven of the Plaintiffs' Second Amended Complaint; and the court WITHHOLDS RULING as to Counts Five and Ten of the Plaintiffs' Second Amended Complaint.

Rather than craft a particular remedy at this time, the court will hold a hearing on August 22, 2006, at 9:00 a.m., as to the appropriate remedies in this case. All parties -- the Plaintiffs, the Defendants, and the Intervenors -- may file briefs, up to fifteen pages in length, discussing their views as to what appropriate remedies should be based on this Order. These briefs should also discuss Counts Five and Ten of the Plaintiffs' Second Amended Complaint (as discussed in note

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16, *supra*). These briefs shall be filed no later than August 17, 2006. All parties may file responsive briefs, up to five pages in length, no later than August 21, 2006 at 12:00 p.m.

IT IS SO ORDERED.

DATED: Honolulu, Hawaii, August 10, 2006.

J. Michael Seabright
United States District Judge