ATTACHMENT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DEFENDERS OF WILDLIFE and AUDUBON OF KANSAS **Plaintiffs** **v.** **LISA P. JACKSON and U.S. ENVIRONMENTAL PROTECTION AGENCY** **Defendants** **LIPHATECH, INC.** **Defendant-Intervenor**	**No. 1:09-cv-01814-ESH (and consolidated case)**

INTERVENOR LIPHATECH, INC.'S STATEMENT OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF LIPHATECH'S CROSS-MOTION TO DISMISS OR FOR SUMMARY JUDGMENT

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DATED: December 15, 2010

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INTRODUCTION

This case consolidates challenges by several Plaintiffs to the decision by Defendant the U.S. Environmental Protection Agency (EPA) on May 13, 2009, to register the pesticide product Rozol Prairie Dog Bait (Rozol), EPA Reg. No. 7173-286, under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136a. Liphatech, Inc. (Liphatech) is the registrant of this pesticide. Plaintiffs, Defenders of Wildlife (Defenders), Audubon of Kansas (Audubon), and Natural Resources Defense Counsel (NRDC) (collectively Plaintiffs), have requested that this Court vacate Liphatech's license to sell and distribute Rozol. As the owner of that license, Liphatech sought and was granted intervention of right in both cases that have been consolidated here.

Rozol Prairie Dog Bait contains the rodenticide chlorophacinone and is labeled for use in controlling black-tailed prairie dogs (*Cynomus ludovicianus*) on rangeland and adjacent non-crop areas in Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming. Rozol was initially registered for control of pocket gophers as Rozol Pocket Gopher Bait under a different EPA registration number, and was subsequently registered for control of black-tailed prairie dogs on rangeland and non-crop areas in six States (Colorado, Kansas, Nebraska, Oklahoma, Texas, and Wyoming) in a series of actions between 2004 and 2008 under FIFRA Section 24(c), 7 U.S.C. § 136v(c). FIFRA Section 24(c) allows individual States to register existing pesticide products for additional uses to address Special Local Needs (SLN). Unless specifically disapproved by EPA, an SLN product becomes a full Federal registration authorizing sale, distribution, and use for the additional use in the specified State. The registrant of an SLN product has the same adjudicatory rights under FIFRA Section 6, 7 U.S.C. § 136d, to request a hearing prior to suspension or cancellation of the license as any

other pesticide registrant. In this instance, when EPA granted the FIFRA Section 3 registration for Rozol, EPA utilized that process to consolidate the six existing SLN registrations under a single registration, and required Liphatech as a condition of registration to cancel voluntarily each of these SLN registrations.

All Plaintiffs claim that FIFRA Section 3(c)(4), 7 U.S.C. § 136a(c)(4), and the related EPA regulations required EPA to provide notice in the Federal Register and an opportunity for submission of comment before granting Liphatech a FIFRA Section 3 registration for Rozol. Two Plaintiffs also claim that EPA did not properly determine that the substantive requirements for registration were met before issuing the FIFRA Section 3 registration.

The Plaintiffs' various FIFRA claims are now moot and must be dismissed. EPA received a petition on June 10, 2009, from the World Wildlife Fund (WWF Petition) requesting that EPA rescind the registration for Rozol, and EPA then elected to publish a notice and to invite public comment concerning this petition. 74 Fed. Reg. 51601 (Oct. 7, 2009); see also 74 Fed. Reg. 57168 (Nov. 4, 2009) (extending comment period). EPA issued a detailed decision concerning this petition on November 16, 2010, in which it responded to the public comments it received, found no basis to initiate suspension or cancellation proceedings for Rozol, and described additional steps EPA would be taking to mitigate potential risks associated with use of Rozol. See Exhibit D to Defendants' Combined Opposition to Plaintiffs' Motion for Summary Judgment and Cross-Motion for Dismissal or Summary Judgment (EPA Mem.). Because EPA made detailed findings and expressly affirmed its prior determination that Rozol meets the statutory standard for registration under FIFRA Section 3, and because this new decision by EPA is itself reviewable, the Plaintiffs' procedural and substantive claims under FIFRA are now moot and should be dismissed.

Even if the Court were to determine that Plaintiffs' claim that EPA was required to provide notice and comment under FIFRA Section 3(c)(4) before granting Liphatech a FIFRA Section 3 registration is not moot, the Plaintiffs have not met their burden to establish the existence of a procedural violation under the applicable statutory provision and EPA regulations. When the procedural history of the FIFRA Section 3 registration and the substantive nature of the additional activities permitted by the registration are considered, there is a rational basis for concluding that EPA had no obligation to provide notice and comment under the applicable legal standard.

The Plaintiffs also claim that EPA was required to consult with the U.S. Fish and Wildlife Service (FWS) under Section 7(a)(2) of the Endangered Species Act (ESA), 16 U.S.C. § 1536(a)(2), before it could lawfully issue the FIFRA Section 3 registration for Rozol. Like the FIFRA claims, the Plaintiffs' claims under ESA Section 7(a)(2) are now moot because EPA has elected to initiate a consultation with the FWS concerning the same registered product. *See* Exhibits A and B to EPA Mem.

Even if the Court were to determine that the Plaintiffs' claims under ESA Section 7(a)(2) are not moot, the Plaintiffs would not be entitled to any relief. The Plaintiffs have fundamentally misconstrued the FWS regulations that establish how the effects of a Federal action that may be subject to consultation are determined, and the Plaintiffs have not established that EPA was required to consult when the correct standard is applied.

Plaintiffs claim that the continued registration of Rozol during the pending consultation with FWS is contrary to the ESA, but any actions by EPA during the consultation process are limited only by ESA Section 7(d), 16 U.S.C. § 1536(d), which prohibits EPA from making "any irreversible or irretrievable commitment of resources." The Plaintiffs have not pled or attempted

to establish any violation of ESA Section 7(d). In any case, it is clear that EPA's decision to grant a FIFRA Section 3 registration did not involve any irreversible or irretrievable commitment because any needed changes in the terms and conditions of registration can be readily accomplished if the consultation process establishes that changes are required.

Finally, two Plaintiffs purport to make claims under the Migratory Bird Treaty Act (MBTA), 16 U.S.C. § 703 *et seq.*, the Bald Eagle and Golden Eagle Protection Act (BGEPA), 16 U.S.C. §§ 668-668d, and Executive Order 13186 (E.O. 13186). The Court lacks subject matter jurisdiction to entertain any of these claims. To the degree that the Court concludes it has jurisdiction to consider claims involving the MBTA and/or the BGEPA as part of its FIFRA jurisdiction, these claims have now become moot along with the Plaintiffs' other substantive allegations under FIFRA. Finally, even if there is some FIFRA claim concerning compliance with the MBTA and the BGEPA that has not become moot, the potential for indirect effects from use of Rozol does not constitute a "take" of relevant species under these statutes.

Defendants EPA and Lisa P. Jackson have moved to dismiss all of the Plaintiffs' claims or, in the alternative, for summary judgment concerning these claims. Liphatech is today making its own motion for dismissal or summary judgment concerning all of the Plaintiffs' claims. In the interest of brevity, Liphatech hereby adopts and incorporates by reference the discussion in the "Statutory and Regulatory Background," "Factual Background," and "Litigation Background" sections in the memorandum supporting the EPA motion. EPA Mem. at 3-11. Although Liphatech disagrees with some EPA analysts on certain scientific issues associated with registration and use of Rozol, Liphatech generally supports the EPA motion as well as the basic legal arguments that EPA has made in support of that motion. Liphatech is filing its own motion and supporting memorandum because there are additional facts and legal precedents

supporting the key arguments made by EPA, and because there are additional grounds for dismissal or summary judgment not adduced by EPA.

JURISDICTIONAL STATEMENT

As discussed below, events subsequent to the issuance of the FIFRA Section 3 registration for Rozol Prairie Dog Bait have caused the Plaintiffs' claims to become moot under Article III of the U.S. Constitution, and the Court is not authorized to issue an advisory opinion concerning any of the Plaintiffs' claims. Federal Courts must consider and resolve the question of Article III jurisdiction before addressing the merits of any claim that may no longer be justiciable. Steel Co. v. Citizens for a Better Environment, 523 U.S. 83, 88-89 (1998).

The Plaintiffs' procedural and substantive claims under FIFRA are now moot. If the Court were to determine that any of the Plaintiffs' FIFRA claims are not moot, this Court has jurisdiction to consider and resolve them. Jurisdiction for the District Court to review the decision of EPA to grant a conditional registration for Rozol Prairie Dog Bait under FIFRA Section 3(c)(7), 7 U.S.C. § 136a (c)(7), is provided by FIFRA Section 16(a), 7 U.S.C. § 136n(a), because decisions to grant initial registration are "final actions of the Administrator not committed to the discretion of the Administrator by law." The assertion by the Plaintiffs that FIFRA Section 16(c), 7 U.S.C. § 136n(c), provides jurisdiction to review the pesticide registration at issue in this case is dubious, because the evident purpose of that section is to allow enforcement actions concerning violations of FIFRA by parties other than EPA. In any case, the District Court has jurisdiction under FIFRA Section 16(a) over any claims concerning the FIFRA Section 3 registration for Rozol Prairie Dog Bait that are not moot.[1]

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[1] Liphatech notes that the District Court may not retain jurisdiction over any claims that are not moot if the Plaintiffs or any other party seeks review of the EPA decision concerning the WWF Petition in the Court of Appeals under FIFRA Section 16(b), 7 U.S.C. §

Jurisdiction concerning any claims by the Plaintiffs under ESA Section 7(a)(2) that are not moot is provided by the citizen suit provision in ESA Section 11(g)(1)(A), 16 U.S.C. § 1540(g)(1)(A).

The Court lacks any subject matter jurisdiction concerning the Plaintiffs' claims under the MBTA, the BGEPA, and E.O. 13186. The Court also lacks subject matter jurisdiction concerning the Plaintiffs' MBTA and BGEPA claims under the Administrative Procedure Act (APA), but any claims concerning compliance by EPA with these statutes that are not moot may be considered as part of the Court's review under FIFRA Section 16(a). Defenders of Wildlife v. EPA, 882 F.2d 1294, 1301-04 (8th Cir. 1989).

The November 16, 2010 decision of EPA concerning the WWF Petition was issued following notice and opportunity for comment. Accordingly, it is reviewable in the D.C. Court of Appeals under FIFRA Section 16(b), 7 U.S.C. § 136n(b). Humane Society v. EPA, 790 F.2d 106, 110-14 (D.C. Cir. 1986); EDF v. Costle, 631 F.2d 922, 925-32 (D.C. Cir. 1980). Any ESA claims that the Plaintiffs may assert in connection with the EPA decision on the WWF Petition would also be heard in the Court of Appeals. Carpenter v. DOT, 13 F.3d 313, 316 (9th Cir. 1994); American Bird Conservancy v. FCC, 545 F.3d 1190 (9th Cir. 2008); Pesticide Action Network v. EPA, 2008 U.S. Dist. LEXIS 98572 (N.D. Ca. 2008).

136n(b). Telecomm. Res. & Action Ctr. (TRAC) v. FCC, 750 F.2d 70, 75 (D.C. Cir. 1984).

STANDARD OF REVIEW

The Court must dismiss any claim for which it determines it lacks subject matter jurisdiction. Fed. R. Civ. P. 12(h)(3). Summary judgment should be entered whenever the Court finds that "there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2).

If the Plaintiffs' claims concerning the EPA registration action at issue here are not deemed to be moot, the general standard governing the Court's review is provided by Section 706 of the APA. APA Section 706(2)(A), 5 U.S.C. § 706(2)(A), requires the Court to determine whether EPA's actions were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." The party asserting an APA challenge bears the burden of demonstrating that the agency's actions violate this standard. City of Olmsted Falls v. FAA, 292 F.3d 261, 271 (D.C. Cir. 2002). Review is generally limited to the administrative record compiled by the agency, Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 419 (1971), *abrogated in part by* Califano v. Sanders, 430 U.S. 99 (1977) (abrogating Overton Park to the extent it recognized the APA as an independent grant of subject matter jurisdiction), although there are some narrow recognized exceptions to this rule. Esch v. Yeutter, 876 F.2d 976, 991 (D.C. Cir. 1989). In conducting its review, the Court is not empowered to substitute its judgment for that of the agency. Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto Ins., 463 U.S. 29, 43 (1983).

In reviewing the agency's construction of a statutory provision, the Court must first determine whether Congress has "directly spoken to the precise question at issue," and if it has not, the Court must determine "whether the agency's answer is based on a permissible construction of the statute." Chevron, USA, Inc. v. NRDC, 467 U.S. 837, 842-45 (1984). In reviewing the agency's interpretation of its own regulations, the Court must give "controlling

weight" to the agency's construction "unless is it plainly erroneous or inconsistent with the regulation." Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994).

ARGUMENT

I. PLAINTIFFS HAVE FAILED TO SHOW ANY PROCEDURAL VIOLATION OF FIFRA AND THEIR PROCEDURAL CLAIMS UNDER FIFRA MUST ALSO BE DISMISSED AS MOOT

A. EPA's Decision to Provide Notice and Comment Before Acting on the WWF Petition Has Made the Plaintiffs' Claims That EPA Was Required to Provide Notice and Comment before Granting the FIFRA Section 3 Registration Moot

Plaintiffs claim that EPA was required to provide notice in the Federal Register and an opportunity for comment concerning the FIFRA Section 3 registration for Rozol Prairie Dog Bait under FIFRA Section 3(c)(4), 7 U.S.C. § 136a(c)(4), and 40 C.F.R. § 152.102 (the EPA regulation that construes and implements that statutory provision). Plaintiffs also contend that 40 C.F.R. § 152.102 required EPA to publish a notice of issuance in the Federal Register when it granted the FIFRA Section 3 registration for Rozol Prairie Dog Bait. Memorandum in Support of Plaintiffs' Motion for Summary Judgment (Pl. Mem.) at 20, 22. Liphatech will show below that Plaintiffs have failed to meet their burden to demonstrate any procedural error under these provisions, and that a proper examination of the nature of the EPA action demonstrates that EPA had no obligation to do any of these things. Nevertheless, the Court does not need to even reach the merits of the Plaintiffs' procedural FIFRA claims because EPA's actions concerning the WWF Petition to cancel have rendered these claims moot.

In order for a U.S. Court to assume jurisdiction concerning a claim, there must be a justiciable "case" or "controversy." U.S. Constitution art. III, § 2. This means that no Court has the authority to render an advisory opinion concerning any claim that is moot. In Flast v. Cohen, 392 U.S. 83 (1968), the Supreme Court described this fundamental jurisdictional limitation:

> [N]o justiciable controversy is presented ... when the question sought to be adjudicated has been mooted by subsequent developments.

392 U.S. at 95. Federal Courts must consider and resolve the question of Article III jurisdiction before addressing the merits of any affected claim. Steel Co., 523 U.S. at 88-89.

In this case, EPA has already provided as part of its review of the WWF Petition for notice in the Federal Register and a full opportunity to comment concerning every substantive issue raised by the Plaintiffs, and EPA has issued a detailed decision responding to comments actually submitted by the Plaintiffs on each of these issues. The decision on the WWF Petition by EPA was anything but perfunctory, because EPA has taken concrete actions that address issues raised by the comments it received, including obtaining amendments in the terms of Liphatech's Section 3 registration, EPA Mem., Exhibit C and Exhibit D at 2, 24-25, requiring development and submission of additional data, EPA Mem., Exhibit D at 2, 25-26, and initiating a consultation under ESA Section 7(a)(2). EPA Mem., Exhibits A & B, Exhibit D at 1. EPA has also issued a risk management determination that expressly affirms its original determination that Rozol Prairie Dog Bait satisfies the statutory standards for registration. The basic standard for registration concerning absence of "unreasonable adverse effects" also governs any decision by EPA to issue a notice of intent to cancel a pesticide registration under FIFRA Section 6(b), 7 U.S.C. § 136d(b), see EPA Mem., Exhibit D at 4, and EPA expressly concluded that initiation of cancellation proceedings for Rozol Prairie Dog Bait is not warranted. EPA Mem., Exhibit D at 2, 24, 25.

When a party claims that an agency has made a procedural error, and the agency later takes "corrective action" by following the very procedure that the party claims was required, there is no longer a justiciable claim. NRDC v. NRC, 680 F.2d 810, 814 (D.C. Cir. 1982). In NRDC v. NRC, the Court found that repromulgation of a rule after notice and comment made

moot the Plaintiff's allegations that the NRC previously failed to provide notice and comment. The Court stated:

> Even if this attack was originally well-founded, we can hardly order the NRC at this point to do something it has already done. ... In effect, NRDC seeks a declaration from this court that the initial promulgation of the rule was unlawful, an advisory opinion which federal courts cannot provide.

680 F.2d at 814-15.[2]

There is no reason to believe that if the Court ordered EPA to provide a further notice and opportunity for comment concerning Liphatech's FIFRA Section 3 registration, this would entail receipt of comment on any issue not already addressed as part of comment on the WWF Petition. Nor is there any reason to believe that EPA would reach different conclusions than those it has already reached in its decision concerning the WWF Petition. The Plaintiffs suggest that the determinations EPA made, and the actions EPA took in response, to the WWF Petition have been tainted because they are mere *post hoc* rationalization. Pl. Mem. at 26-27. This characterization cannot be reconciled with the extensive record compiled by EPA, or the careful and deliberate nature of EPA's explanation. In any case, as explained above, that decision is reviewable by a petition filed in the Court of Appeals under FIFRA Section 16(b), 7 U.S.C. § 136n(b).[3]

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[2] Liphatech recognizes that there are some narrow exceptions to the mootness doctrine, but these do not apply here. In particular, there is no reason to believe that Plaintiffs' FIFRA procedural claims are "capable of repetition, yet evading review." Southern Pacific Terminal Co. v. ICC, 219 U.S. 498, 515 (1911). Nothing in this record suggests that dismissal of this action will cause EPA to disregard notice and comment requirements for any future FIFRA registrations that may be subject to them, nor is there any reason to believe that such procedural errors (if they occur) would be of sufficiently limited duration to preclude judicial review. *See* NRDC v. NRC, 680 F.2d at 814, n.8.

[3] Dismissal of Plaintiffs' FIFRA claims for mootness is also desirable as a prudential matter, because it avoids other serious jurisdictional problems created by the possibility that the Plaintiffs or another party will seek review of the EPA decision concerning the

The Plaintiffs will no doubt claim that their FIFRA procedural claims are not moot because the Court can still provide effective relief by vacating Liphatech's FIFRA Section 3 registration. This argument implicitly presumes that vacatur would be a lawful and appropriate remedy for any alleged procedural error. As Liphatech will show below, vacating the FIFRA Section 3 registration for Rozol without reinstating the six cancelled State SLN registrations would violate the adjudicatory rights of Liphatech, be inappropriate for other reasons, and likely be futile in giving Plaintiffs the relief they seek.

Whatever the merits of Plaintiffs' FIFRA procedural claims, they have been effectively extinguished by the decision of EPA to provide notice and opportunity for comment concerning the WWF Petition. There is no longer a justiciable case or controversy concerning any purported procedural error under FIFRA Section 3(c)(4) and 40 C.F.R. § 152.102, and the Plaintiffs' claims concerning violation of these provisions must be dismissed as moot.

B. Even If Plaintiff's Procedural FIFRA Claims Are Not Moot, EPA Had No Obligation to Provide Notice or Opportunity for Comment Concerning Liphatech's Application for a FIFRA Section 3 Registration

Even if the Court were to determine for some reason that the Plaintiffs' procedural FIFRA claims are not moot, the Court should enter summary judgment against Plaintiffs on these claims. The Plaintiffs have expressly acknowledged that they have the burden of establishing the existence of a procedural violation by showing that the circumstances that would trigger the requirements of FIFRA Section 3(c)(4) and 40 C.F.R. § 152.102 exist. Pl. Mem. at 13, citing Thomas v. Peterson, 753 F.2d 754, 765 (9th Cir. 1985). Nevertheless, the Plaintiffs have done

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WWF Petition in the Court of Appeals. TRAC v. FCC, 750 F.2d at 75 ("where a statute commits review of agency action to the Court of Appeals, any suit seeking relief that might affect the Circuit Court's future jurisdiction is subject to the *exclusive* review of the Court of Appeals").

nothing to satisfy this burden. Rather than evaluating the applicability of the language of these provisions to the facts concerning Liphatech's FIFRA Section 3 registration, the Plaintiffs' have only made conclusory assertions that these provisions apply. Pl. Mem. at 6 ("EPA indisputably was undertaking a new registration for a new use.")

Plaintiffs also misrepresent the facts when they repeatedly state, "EPA concedes that it did not follow FIFRA's procedural requirements." Pl. Mem at 19; see also Pl. Mem at 22 (stating that "EPA concedes that it violated the procedural requirements of FIFRA."). As EPA notes in its Memorandum, EPA has conceded nothing of the kind. Rather, EPA clearly states: "[U]nder the governing statutory and regulatory provisions discussed above -- no notice or opportunity for public comment was required in this case, at least with respect to the states for which prior SLN registrations existed." EPA Mem. at 25.

EPA's construction of the applicable legal provisions is critical here. Unless the precise language of FIFRA Section 3(c)(4) supports a conclusion that it clearly applies to Liphatech's Section 3 registration application, this Court must defer to EPA's interpretation of FIFRA Section 3(c)(4) if it is "based on a permissible construction of the statute." Chevron v. NRDC, 467 U.S. at 843-45. Moreover, the Court must give "controlling weight" to EPA's construction of 40 C.F.R. § 152.102 and 40 C.F.R. § 152.3 "unless is it plainly erroneous or inconsistent with the regulation." Thomas Jefferson, 512 U.S. at 512.

FIFRA Section 3(c)(4) states:

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

EPA has construed and effectuated FIFRA Section 3(c)(4) by adopting 40 C.F.R. § 152.102, which states:

> The Agency will issue in the Federal Register a notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use. After registration of the product, the Agency will issue in the Federal Register a notice of issuance. The notice of issuance will describe the new chemical or new use, summarize the Agency's regulatory conclusions, list missing data and the conditions for their submission, and respond to comments received on the notice of application.

The term "new use" in 40 C.F.R. § 152.102 is defined by 40 C.F.R. § 152.3, which states:

> *New use*, when used with respect to a product containing a particular active ingredient, means:
> (1) Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of a tolerance or food additive regulation under section 408 of the Federal Food, Drug and Cosmetic Act;
> (2) Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or
> (3) Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.

Chlorophacinone, the active ingredient in Rozol, was registered for decades prior to receipt of Liphatech's FIFRA Section 3 application for Rozol Prairie Dog Bait, so this application did not involve a new active ingredient. For this reason alone, NRDC v. EPA, 676 F. Supp. 2d 307 (S.D.N.Y. 2009), is inapposite to the facts of this case. That case involved the failure of EPA to provide notice and opportunity for comment concerning registration of a totally new active ingredient. Moreover, use of Rozol to control prairie dogs is not a food use and does not require a tolerance or exemption from a tolerance, so it could not be deemed a "new use" of an existing active ingredient on this basis.

Use of chlorophacinone to control black-tailed prairie dogs on rangeland and adjacent non-crop areas also could not be deemed to be a "new use" because "no product containing the active ingredient is currently registered for that use pattern." Six SLN products with the same

composition as Rozol Prairie Dog Bait were registered for use in controlling black-tailed prairie dogs on rangeland and non-crop areas in Colorado, Kansas, Nebraska, Oklahoma, Texas, and Wyoming on the date of receipt of Liphatech's Section 3 application to register Rozol Prairie Dog Bait. Administrative Record (AR)[4] 23, 41, 48, 55, 59, and 65. Because EPA did not disapprove these SLN registrations under FIFRA Section 24(c)(2), 7 U.S.C. § 136v(c)(2), and 40 C.F.R. § 162.154(c), these SLN registrations became full Federal registrations under FIFRA Section 24(c)(1), 7 U.S.C. § 136v(c)(1), and 40 C.F.R. § 162.152(c)(1). EPA explicitly construes both FIFRA Section 3(c)(4) and the definition of a "new use" in 40 C.F.R. § 152.3 to require consideration of these SLN registrations. EPA Mem. at 25-26. This construction by EPA is not only "permissible" -- it is the only reasonable construction of these provisions.

The only remaining part of the definition of a "new use" that could conceivably apply to Liphatech's Section 3 application for Rozol Prairie Dog Bait is: "Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms." 40 C.F.R. § 152.3. The only basis for concluding there would be a change in either the level of exposure or the route of exposure is that the Section 3 registration for Rozol Prairie Dog Bait allowed use in four additional States (Montana, New Mexico, North Dakota, and South Dakota). There is no basis in the record for any suggestion that registration in these four additional States would result in any "change in the route of exposure," so the sole issue is whether the registration in these four

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[4] This refers to the Certified Amended Index to the Administrative Record filed by Defendants on October 29, 2010. As required by Local Rule 7(n), the parties will file a deferred Joint Appendix containing appropriate excerpts from the AR after all briefing is complete.

additional States would cause a "significant increase in the level of exposure ... to the active ingredient of man or other organisms." 40 C.F.R. § 152.3.

Because none of these four additional States had previously acted to grant an SLN registration for control of black-tailed prairie dogs, it was reasonable for EPA to infer that any use of the product in these four States would be far less extensive than in the six existing States. As noted above, EPA's interpretation of what the word "significant" means must be given controlling weight. Plaintiffs have given no explanation of why they believe that use in the four additional States would result in "a significant increase in the level of exposure."[5]

Fortunately, it is possible to examine information collected since the approval of the FIFRA Section 3 registration to determine whether there has in fact been a "significant increase" in exposure as a result of use in the four additional States. Although such information is not part of the certified administrative record, it falls within one of the recognized exceptions for extra-record evidence: "cases where evidence arising after the agency action shows whether the decision was correct or not." Esch v. Yeutter, 876 F.2d at 991; Fund for Animals v. Williams, 391 F. Supp. 2d 191, 198 (D.D.C. 2005).

The attached Declaration of Thomas Schmit (Schmit Declaration), Exhibit A to this Memorandum, specifically addresses the question of use of Rozol Prairie Dog Bait in the four additional States. Although the FIFRA Section 3 registration for Rozol Prairie Dog Bait was granted in May 2009, all product shipped into channels of trade for use in controlling black-tailed prairie dogs prior to August 2009 was Rozol Pocket Gopher Bait accompanied by the

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5 Plaintiffs argue that approval of the Section 3 registration for Rozol "greatly expand[ed] the use area," Pl. Mem. at 5, but this is not the applicable standard. Plaintiffs have acknowledged that they must establish that "the circumstances triggering the procedural requirement exist." Pl. Mem. at 13.

relevant State SLN labels. Thus, there could not have been any increase in exposure from use in the four additional States prior to August 2009. Schmit Declaration at ¶ 10.

No sales or usage of Rozol Prairie Dog Bait have occurred in Montana because this product does not yet have a Montana State registration. Rozol Prairie Dog Bait has not been shipped directly to North Dakota, and there is no evidence that it has been used in North Dakota. Based on aggregate sales figures for stocks of Rozol Prairie Dog Bait shipped between August 2009 and September 2010, only 3.6 percent of these stocks were shipped to South Dakota and only 0.1 percent of these stocks were shipped to New Mexico. Thus, the best available estimate is that only 3.7 percent of the stocks of Rozol Prairie Dog Bait shipped between August 2009 and September 2010 will be used in the four additional States. Schmit Declaration at ¶ 12.

EPA had a rational basis for concluding that use of Rozol Prairie Dog Bait in the four additional States not covered by the existing SLN registrations would not result in a "significant increase in the level of exposure."[6] The Plaintiffs have provided no evidence to the contrary. EPA Mem. at 26-27. In contrast, the data concerning actual sales in the Schmit Declaration show that the four additional States account for only 3.7 percent of total sales of the product. It

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[6] The Plaintiffs may argue that the record does not contain any document explaining why the use of Rozol in the four additional States would not involve a "significant increase" in exposure. EPA should not be required to document its rationale for every determination that it makes that a particular procedural requirement does not apply. Moreover, if EPA erred by failing to explain why use in the four additional States should not be deemed a "significant increase," the Court need not disturb the result if it can determine that the outcome would be the same in the absence of the error. Green Island Power Auth. v. FERC, 577 F.3d 148, 165 (2d Cir. 2009). In any case, since there is a rational and plausible basis for concluding that FIFRA Section 3(c)(4) and 40 C.F.R. § 152.102 did not apply to Liphatech's Section 3 registration application, and rescinding the registration would be highly disruptive, the correct remedy for any purported deficiency in the record concerning this issue would be to remand to EPA for further explanation rather than vacating the registration. Northeast Md. Waste Disposal Auth. v. EPA, 358 F.3d 936, 949-50 (D.C. Cir. 2004).

strains credibility to suggest that EPA was required to construe such a small proportion of total use as a "significant increase in the level of exposure."

C. Because EPA Required Liphatech to Cancel Its SLN Registrations for Rozol to Receive a Section 3 Registration, the Relief Requested by Plaintiffs Would Violate Liphatech's Adjudicatory Rights under FIFRA

Even if it assumed for the sake of argument that the Plaintiffs' FIFRA procedural claims are not moot and have some merit, the Court could not grant the Plaintiffs' request that the FIFRA Section 3 registration be vacated without considering the collateral effect of such relief on the adjudicatory rights of Liphatech. The six SLN registrations that were in effect when Liphatech applied for the FIFRA Section 3 registration were full Federal registrations that could not be suspended or cancelled without affording Liphatech an opportunity for a formal adjudicatory hearing under FIFRA Section 6. 40 C.F.R. § 162.152(c)(1). Because EPA wanted to consolidate these SLN registrations in a Federal registration, EPA expressly required that Liphatech submit voluntary requests to cancel each of the SLN registrations as one of the conditions of the Section 3 registration. AR 86 at 1.[7]

If the Court were to vacate the FIFRA Section 3 registration without also ordering EPA to reinstate the six SLN registrations, this would not restore the status quo prior to EPA's issuance of the Section 3 registration. Such relief would deprive Liphatech of its adjudicatory rights concerning the SLN registrations under FIFRA Section 6. EPA itself has recognized this serious problem with the relief requested by the Plaintiffs:

> [I]f the Court were to grant the vacatur sought by Plaintiffs, leaving Rozol with no valid registration at present, this action would, under the circumstances, deprive

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7 As required by FIFRA Section 6(f)(1), 7 U.S.C. § 136d(f)(1), EPA published a notice concerning these requests for voluntary cancellation, 75 Fed. Reg. 5318 (Feb. 2, 2010), and the cancellation of these SLN registrations became effective on October 14, 2010. 75 Fed. Reg. 63178 (Oct. 14, 2010).

> LiphaTech of the procedural remedies Congress required in FIFRA before existing registrations can be suspended or cancelled.

EPA Mem. at 20.

Granting vacatur of the FIFRA Section 3 registration without also ordering reinstatement of the SLN registrations would also be expressly contrary to APA Section 558(c), 5 U.S.C. § 558(c), which states:

> When the licensee has made timely and sufficient application for a renewal or a new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been finally determined by the agency.

In these factual circumstances, the Court cannot grant the relief requested by the Plaintiffs without also ordering EPA to reinstate the six SLN registrations. Any other course would fundamentally violate the procedural rights of Liphatech under FIFRA Section 6 and APA Section 558(c).

D. Even If Vacatur Was a Legally Permissible Form of Relief for Any Purported Failure of EPA to Provide Notice and Comment Concerning the Section 3 Registration, Vacatur Would Be an Inappropriate Remedy

If it is assumed that Plaintiffs' FIFRA procedural claims are not moot, that there was some requirement to provide notice and comment concerning the FIFRA Section 3 registration, and that the Section 3 registration could be lawfully vacated without addressing the impact of this relief on Liphatech's adjudicatory rights under FIFRA and the APA, the Court would still have to consider whether vacatur would be an appropriate remedy in this instance. There are two compelling reasons why it would not.

First, the Court should consider the severe disruptive effects of vacatur in determining whether this form of relief is appropriate. The Court should take account of the fact that black-tailed prairie dogs are a potential public health threat because they are "hosts for fleas that may

vector plague." AR 7 at 2. Black-tailed prairie dog colonization can also severely impact the suitability of rangeland for livestock. EPA has estimated that "when 60% of pasture is colonized by prairie dogs, the loss in net operating revenue compared to un-colonized pastures reaches nearly 30%." EPA Mem., Exhibit D at 21. The reason why States originally registered SLN products is that users "have not been able to adequately keep increasing populations of black-tailed prairie dogs in check in recent years." AR 32 at 3. There are quite serious concerns regarding the safety of the registered alternatives, including the possibility that applicators will be exposed to poisonous fumes and the fire hazard associated with use of gas cartridges. AR 32 at 2, 5; EPA Mem., Exhibit D at 23. Moreover, the hazard of primary toxicity to non-target wildlife is actually far greater from use of baits containing zinc phosphide (the principal alternative used to control black-tailed prairie dogs) than from chlorophacinone (the active ingredient in Rozol Prairie Dog Bait). AR 32 at 8-9; AR 81A at 107. The Court should consider all of these factors before granting any relief that would require that existing users of Rozol either forego control of black-tailed prairie dogs or use alternatives that involve significant hazards.

Second, there has been no showing by the Plaintiffs that any purported procedural error has actually caused meaningful prejudice to the Plaintiffs. When a court reviewing agency action applies the standard of review set forth in the APA, "due account shall be taken of the rule of prejudicial error." Section 706(2), 5 U.S.C. § 706(2). The burden of demonstrating that there has been prejudicial error is on the party challenging the agency action. Jicarilla Apache Nation v. DOI, 613 F.3d 1112, 1121 (D.C. Cir. 2010).

It is not enough for the Plaintiffs to state that they oppose the continued use of Rozol Prairie Dog Bait, and therefore they are prejudiced by its continued registration. To obtain relief,

Plaintiffs must show that they have been prejudiced by EPA's specific action in granting Liphatech a FIFRA Section 3 registration. As discussed above, it is clear that if EPA had not granted Liphatech a Section 3 registration for Rozol Prairie Dog Bait, the six State SLN registrations would still be in effect. Thus, the only prejudice that Plaintiffs could conceivably show from the EPA action in granting a Section 3 registration must necessarily relate to use of Rozol Prairie Dog Bait in the four additional States not covered by the SLN registrations. The Schmit Declaration demonstrates that there has been no meaningful prejudice, because actual use of Rozol in these four States constitutes only 3.7 percent of total use of the product. Schmit Declaration at ¶ 12.

Plaintiffs have not identified any unique or unusual impacts in the two additional States where Rozol is actually being used to control black-tailed prairie dogs that would warrant a conclusion that this small quantity of additional use is prejudicial to the Plaintiffs. Thus, Plaintiffs have not sustained their burden to show that the purported procedural error was sufficiently prejudicial to warrant the relief they have requested. PDK Labs. V. DEA, 362 F.3d 786, 799 (D.C. Cir. 2004) ("If the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration.")

E. Vacatur Would Be Futile in Any Case Because the Individual States Would Likely Reissue SLN Registrations, and EPA Has No Lawful Basis for Disapproving New SLN Registrations

Finally, the Court must consider whether, even if there is some purported procedural error that is not moot and would warrant some sort of relief, the relief requested by the Plaintiffs would ultimately be futile in light of EPA's actions concerning the WWF Petition. Even if the Court were to decline to order reinstatement of the SLN registrations that were in place at the time EPA granted the FIFRA Section 3 registration, nothing would preclude Liphatech from

seeking new SLN registrations if the FIFRA Section 3 registration was vacated. See EPA Mem. at 19. Given the detailed determinations already made by EPA in its decision concerning the WWF Petition, there would be no legitimate basis for EPA to disapprove registration of new SLN products. Given these factors, it is probable that nothing of consequence would be achieved if the Court were to provide the Plaintiffs with the relief they seek.

II. THE SUBSTANTIVE FIFRA CLAIMS MADE BY SOME PLAINTIFFS ARE INDISPUTABLY MOOT IN LIGHT OF EPA'S DECISION ON THE WWF PETITION

In addition to their procedural claims, Plaintiffs Defenders and Audubon also assert substantive claims under FIFRA. They argue that the EPA administrative record does not include findings that Rozol Prairie Dog Bait satisfies the standards for registration set forth in FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5). Pl. Mem. at 22-25. Specifically, these Plaintiffs argue that EPA did not make any findings concerning the absence of "unreasonable adverse effects" under FIFRA Section 3(c)(5)(C) & (D), 7 U.S.C. § 136a(c)(5)(C) & (D). "Unreasonable adverse effects on the environment" is defined by FIFRA Section 2(bb), 7 U.S.C. 136(bb)(1), as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[8]

At the outset, it is important to note that Rozol Prairie Dog Bait was actually conditionally registered under FIFRA Section 3(c)(7), 7 U.S.C. § 136a(c)(7). AR 86 at 1. This provision allows EPA to register a product if "the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways

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[8] Plaintiffs appear to argue that risk information alone can constitute "evidence that Rozol does cause 'unreasonable adverse effects on the environment.' " Pl. Mem. at 23. This assertion is incorrect, because a determination concerning "unreasonable adverse effects" intrinsically requires that EPA balance information concerning potential risks against information concerning benefits.

that would not significantly increase the risks of unreasonable adverse effects on the environment." FIFRA Section 3(c)(7)(A), 7 U.S.C. § 136a(c)(7)(A)(i). This provision also allows EPA to issue a new registration for a product with an existing active ingredient if all data required to support that registration are under development and EPA requires that such supporting data be submitted according to the same schedule.

EPA processes thousands of applications every year for registration or amended registration under FIFRA Section 3(c)(7), 7 U.S.C. § 136a(c)(7), and it would be impractical and unreasonable to require that EPA prepare a detailed and contemporaneous decision document supporting each such action. If the written record for such an application establishes that EPA had a rational basis for its decision to grant a conditional registration that should suffice. In any case, any allegation that the administrative record for the FIFRA Section 3 registration for Rozol Prairie Dog Bait does not contain the detailed analysis of risks and benefits required to support EPA's decision is clearly moot given EPA's subsequent actions concerning the WWF Petition.

EPA clearly stated in its initial notice concerning the WWF Petition that its response to that Petition would "address its risk-benefit analysis for this pesticide." 74 Fed. Reg. at 51602. The decision concerning the WWF Petition subsequently issued by EPA, EPA Mem., Exhibit D, reflects a careful and deliberate consideration of all comments, and also addresses all of the substantive issues identified by the Plaintiffs in this case. The basic "unreasonable adverse effects" standard also governs any decision by EPA to issue a notice of intent to cancel a pesticide registration under FIFRA Section 6(b), 7 U.S.C. § 136d(b), and EPA's risk management decision concerning the WWF Petition expressly concluded that initiation of cancellation proceedings for Rozol Prairie Dog Bait is not warranted. EPA Mem., Exhibit D at 2, 24, 25.

Thus, the detailed EPA determination on the WWF Petition effectively supplants any prior substantive determinations on the registrability of Rozol Prairie Dog Bait. The decision was issued following notice and extensive comment, and it is supported by a detailed response to the comments received. The Plaintiffs assert that "*post hoc* comment also cannot cure EPA's substantive violation of FIFRA," Pl. Mem. at 27, but this argument is unconvincing. EPA has already reviewed all of the substantive evidence it would review, and made all of the regulatory determinations that it would make, if the Court were to vacate and remand the FIFRA Section 3 registration for further action. The Plaintiffs cannot assert that any purported error in providing notice and comment was prejudicial unless there is some credible basis for concluding that the outcome would have been different. PDK Labs. V. DEA, 362 F.3d at 799; Green Island Power, 577 F.3d at 165.

The EPA decision concerning the WWF Petition is comprehensive and definitive. This new decision is itself susceptible to judicial review under FIFRA Section 16(b), 7 U.S.C. § 136n(b). Even if the Court were to find that some of the purported procedural errors made by EPA remain reviewable, no legitimate basis remains for review of the Plaintiffs' substantive FIFRA claims. These claims must be dismissed as moot.

III. THE PLAINTIFFS' CLAIM THAT EPA FAILED TO CONSULT UNDER ESA SECTION 7(a)(2) IS NOW CLEARLY MOOT AND MUST BE DISMISSED

A. Even If EPA Had an Obligation to Consult Concerning the Section 3 Registration, EPA's Subsequent Decision to Consult Has Made Plaintiffs' Claims under ESA Section 7(a)(2) Moot

The Plaintiffs claim that EPA improperly failed to initiate consultation with FWS under ESA Section 7(a)(2), 16 U.S.C. § 1536(a)(2), concerning Liphatech's FIFRA Section 3 application for registration of Rozol Prairie Dog Bait before EPA granted the registration. Pl. Mem at 13-18. Although Liphatech will show below that EPA had no obligation to consult with

FWS under ESA Section 7(a)(2) concerning the FIFRA Section 3 registration for Rozol, the Court does not need to reach this claim. EPA has now elected to initiate an optional formal consultation with FWS under ESA Section 7(a)(2) concerning the same registered product pursuant to 50 C.F.R. § 402.46. *See* Exhibits A & B, EPA Mem. The applicable precedents clearly establish that the obligation to consult established by ESA Section 7(a)(2) is only procedural, and that any claim that an agency failed to consult is completely extinguished by the actual initiation of the consultation process.

A consistent line of cases establishes that, once an agency has initiated the consultation process under ESA Section 7(a)(2), any claim that the agency should have previously initiated such a consultation becomes moot. Southern Utah Wilderness Alliance v. Smith, 110 F.3d 724, 727-28 (10th Cir. 1997); Southwest Ctr. For Biological Diversity v. U.S. Forest Service, 82 F. Supp. 2d 1070, 1079 (D. Az. 2000); American Littoral Society v. EPA, 199 F. Supp. 217, 244-249 (D. N.J. 2002); Defenders of Wildlife v. Martin, 454 F. Supp. 2d 1085, 1102-05 (E.D. Wa. 2006). Plaintiffs' claims under ESA Section 7(a)(2) are now moot, even though the Plaintiffs argue that the consultation should have been initiated before rather than after the granting of the FIFRA Section 3 registration for Rozol. Southern Utah, 110 F.3d at 729; American Littoral, 199 F. Supp. 2d at 247.

Although the last of these four precedents involved one of the present Plaintiffs, the Plaintiffs have not addressed any of these cases, nor do they cite any countervailing precedent on the basic jurisdictional question of mootness. They argue only that "EPA's belated initiation of consultation with FWS does not cure the agency's Section 7 violation" because "[t]he consultation remains underway, with no set time for completion." Pl. Mem. at 18. This is beside

the point. Once an agency has initiated even an informal consultation, the consultation requirement has been satisfied:

> Plaintiff also argue that even if post-hoc consultation is permitted, such consultation is not concluded in New Jersey .... Completion, however is not required for a finding of mootness. EPA has initiated informal consultation in accordance with the relevant regulations.

American Littoral, 199 F. Supp. 2d at 247.

No purpose would be served if the Court were to order EPA to commence a consultation that is already in progress. *See* Defenders and Audubon Complaint, Prayer for Relief at ¶ D; NRDC Complaint, Request for Relief at ¶ D. Since the consultation that the Plaintiffs claim was required by ESA Section 7(a)(2) is now underway, the Court may not issue an advisory opinion or enter judgment concerning any claim by the Plaintiffs that such consultation was previously required. The Court must dismiss the Plaintiffs' claims under ESA Section 7(a)(2) as moot.

B. If Plaintiffs' Claims under ESA Section 7(a)(2) Are Not Moot, EPA Had No Obligation to Consult Concerning the FIFRA Section 3 Registration Because Plaintiffs Have Incorrectly Construed the Effects Attributable to That Action

Even if the Court were to determine that Plaintiffs' claims concerning ESA Section 7(a)(2) are not moot, and to reach the merits of these claims, EPA was not required to initiate a consultation under this provision before granting the FIFRA Section 3 registration for Rozol Prairie Dog Bait. As in the case of Plaintiffs' FIFRA Procedural claims, Plaintiffs misrepresent EPA's admissions when they state that, "EPA admits it failed to comply with its consultation duties under the ESA." Pl. Mem. at 17. EPA's admission that it did not initiate consultation before granting Liphatech's FIFRA Section 3 registration does not constitute an admission that such a consultation was legally required. Moreover, it should be obvious that the discretionary decision of EPA to commence a subsequent consultation under ESA Section 7(a)(2) also does

not establish that such a consultation was legally required. *See* National Assoc. of Home Builders v. EPA, 551 U.S. 644, 659 (2007).

To the contrary, the administrative record concerning the FIFRA Section 3 registration for Rozol Prairie Dog Bait demonstrates that no consultation under ESA Section 7(a)(2) was required. Plaintiffs assert that consultation was necessary only because they have materially misconstrued the effects attributable to this action under the applicable FWS regulations.

Granting of a license like a pesticide registration is among those "actions" concerning which consultation under ESA Section 7(a)(2) may be required. 50 C.F.R. § 402.02 (*Action* defined to include "the granting of licenses"). Nevertheless, in determining what effects are potentially attributable to a proposed action, the same FWS regulation defines the "effects of the action" as follows:

> *Effects of the action* refers to the direct and indirect effects of an action on the species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action, that will be added to the environmental baseline. The environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation in process.

50 C.F.R. § 402.02. This phrase -- "effects of the action" -- is used to describe the purpose of a biological assessment prepared by FWS, 50 C.F.R. § 402.12(a), the contents of such an assessment, 50 C.F.R. § 402.12(f)(4), and the analytic responsibilities of FWS when a formal consultation is undertaken. 50 C.F.R. § 402.14(g)(3). Moreover, when EPA utilizes the alternative formal consultation process in 50 C.F.R. § 402.46 (as it has now done here), the "effects determination" that is transmitted by EPA to FWS is supposed to address "the effects of a FIFRA action." 50 C.F.R. § 402.40(b).

Determining which effects are actually attributable to an action concerning which an agency may need to consult is a critical step in the analytic process. Plaintiffs simply assume without any analysis that the effects that might trigger a consultation obligation are effects in every State for which EPA granted a FIFRA Section 3 registration. Pl. Mem. at 17. This ignores the fact that, under the definition in 50 C.F.R. § 402.02, "past and present impacts" of Federal actions are included in the "environmental baseline." The actual "effects of the action" are those that "will be added to the environmental baseline" by the proposed action.

As explained above, six SLN products identical in composition to the registered product that is the subject of this litigation were registered for use in controlling black-tailed prairie dogs on rangeland and non-crop areas in Colorado, Kansas, Nebraska, Oklahoma, Texas, and Wyoming on the date of receipt of Liphatech's Section 3 application to register Rozol Prairie Dog Bait. AR 23, 41, 48, 55, 59, and 65. The effects of use of this product in those six States were part of the "environmental baseline" to be used in evaluating whether the effects of use of the product in four additional States (Montana, New Mexico, North Dakota, and South Dakota) would cause jeopardy to the continued existence of an endangered or threatened species. Liphatech has clearly established that incremental use in the four additional States has been very limited. Schmit Declaration at ¶ 12. Moreover, Plaintiffs have not made any allegation that use in any of these four States would have an adverse impact on any listed species, even in conjunction with the effects of the use in six other States permitted by the prior Federal actions approving six SLN registrations.

The subsequent discretionary decision by EPA to initiate consultation concerning use of Rozol Prairie Dog Bait in all ten States does not establish that any duty EPA might have had to

consult concerning the FIFRA Section 3 registration encompassed all ten States.[9] The applicable regulations clearly state that for an "optional formal consultation" initiated by EPA under 50 C.F.R. § 402.46, "EPA shall determine the nature and scope of a FIFRA action." 50 C.F.R. § 402.40(c). Plaintiffs may contend that EPA should have initiated consultation under ESA Section 7(a)(2) concerning approval of some or all of the prior SLN registrations, but they have not pled any failure by EPA to consult concerning those registrations and the subsequent cancellation of these registrations would render any such contention moot. See American Littoral, 199 F. Supp. 2d at 247, n.17. In any case, EPA has the discretion to define the scope of a consultation concerning pesticide registrations, and EPA may therefore elect to address any potential duty it may have had to consult for the prior SLN registrations in the current consultation.

Even if the Court determines that Plaintiffs' claims under ESA Section 7(a)(2) are not moot, Plaintiffs have not properly evaluated the incremental effects attributable to the FIFRA Section 3 registration in making those claims. If the Plaintiffs' claims are not moot, the Court should enter summary judgment against them on this issue.

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[9] Liphatech has previously raised a number of scientific issues concerning the evaluation of potential ecological effects of Rozol by analysts in EPA's Environmental Fate and Effects Division, and these concerns have not been properly addressed in either the effects determination recently transmitted to FWS, or the ecological effects analysis underlying EPA's decision on the WWF Petition. These concerns include the use of implausible assumptions in evaluating the potential for secondary toxicity, unsubstantiated speculation concerning direct access to bait by non-target species, and failure to consider properly actual data on predation associated with other uses of chlorophacinone baits. See AR 43. Because neither the pending consultation with FWS, nor the EPA decision on the WWF Petition, is presently before the Court, there is no present need for the Court to consider or resolve the sufficiency of EPA's response to these comments.

C. Potential Effects Occurring after Consultation Are Governed Exclusively by ESA Section 7(d) and Plaintiffs Have Not Pled Any Claim under This Provision

Plaintiffs contend that their ESA Section 7(a)(2) claim is still justiciable because "Rozol remains on the market and listed species remain at risk." Pl. Mem. at 18. This argument ignores the fact that agency actions following consultation are governed instead by ESA Section 7(d), 16 U.S.C. § 1536(d), which prohibits an agency from making "any irreversible or irretrievable commitment of resources" which would have "the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures." ESA Section 7(d), 16 U.S.C. § 1536(d), allows non-jeopardizing actions to continue during the consultation process. Washington Toxics Coalition v. EPA, 413 F.3d 1024, 1035 (9th Cir. 2005); Southwest Center for Biological Diversity, 307 F.3d 964, 973 (9th Cir. 2002), *opinion withdrawn as moot*, 355 F.3d 1203 (9th Cir. 2004). In Defenders v. Martin, the Court evaluated the relation between the duty to consult under Section 7(a)(2) and the substantive prohibition in Section 7(d), 454 F. Supp. 2d at 1095-97, and expressly based its conclusion that the Plaintiffs' ESA Section 7(a)(2) claims were moot on the continued application of Section 7(d) to actions following consultation. 454 F. Supp. 2d at 1104.

In this case, the Plaintiffs have not pled any violation of ESA Section 7(d). Nor have they specifically addressed the question of whether the approval of the FIFRA Section 3 registration for Rozol Prairie Dog Bait constituted an irreversible or irretrievable commitment of agency resources. In these circumstances, any claim by the Plaintiffs based on the actual effects of the continued use of Rozol on listed species must be dismissed.

D. In Any Case, EPA Has Not Made Any Irreversible or Irretrievable Commitment of Resources in Connection with Liphatech's Section 3 Registration That Would Violate ESA Section 7(d)

Even if the Plaintiffs were to propound a proper claim under ESA Section 7(d), there is no evidence that the continued registration of Rozol Prairie Dog Bait constitutes an irreversible or irretrievable commitment of resources in violation of this provision. The approved labeling of this product has always contained an explicit prohibition addressing use of the product "within prairie dog towns in the range of the black-footed ferret." AR 86, at 6. Moreover, the approved labeling was recently amended to include several changes that will mitigate any risk to non-target species. EPA Mem., Exhibit C and Exhibit D, at 2, 24. There is no evidence that EPA will not make, or that Liphatech will not cooperate with, any additional modifications to the terms and conditions that FWS may determine are necessary to address potential risks to listed species.

Like livestock grazing, use practices for Rozol Prairie Dog Bait are "flexible and can be altered during the process if necessary." Southwest Center, 307 F.3d at 973. This is not an instance "where once action is initiated there can be no turning back, as in a case where timber is cut." *Id.*

In any case, even if some potential violation of ESA Section 7(d) was properly pled and then shown, vacatur of the entire registration would not be a reasonable or permissible remedy. Any remedy must be narrowly tailored to address only the putatively violative conduct.

IV. THE CLAIMS MADE BY CERTAIN PLAINTIFFS BASED ON THE MBTA, THE BGEPA, AND E.O. 13186 MUST BE DISMISSED

A. This Court Lacks Subject Matter Jurisdiction to Consider Claims Based Directly on the MBTA, the BGEPA, and E.O. 13186

Plaintiffs Defenders and Audubon purport to make claims based on the MBTA, the BGEPA, and E.O. 13186. Pl. Mem. at 27-30. Nothing in either the MBTA or the BGEPA creates any private right of action, and federal agency compliance with E.O. 13186 is unreviewable.

The Plaintiffs concede that there is no private right of action under the MBTA and the BGEPA, so they purport to base their jurisdiction on these statutes in combination with the APA. Pl. Mem. at 28. Plaintiff Defenders has made this same argument before in a FIFRA case, and it was rejected. Defenders v. EPA, 882 F.2d at 1301-04. In that case, the Court considered claims related to EPA's registration of pesticide products containing strychnine, and held that the Plaintiffs could obtain review of any purported violation of the MBTA and the BGEPA as part of the judicial review explicitly authorized by FIFRA. The Court stated:

> [W]e believe that review under the APA is precluded. *Section 704* of the APA provides: "agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to review." 5 U.S.C. § 704 (1982). Because FIFRA provides a framework for obtaining judicial review, the district court had no jurisdiction to consider these claims.

Defenders v. EPA, 882 F.2d at 1302.

The Plaintiffs do not address this controlling precedent. Rather, they rely on Humane Society of the U.S. v. Glickman, 217 F.3d 882 (D.C. Cir. 2000), and Center for Biological Diversity v. Pirie, 191 F. Supp. 2d 161 (D.D.C. 2002); vacated as moot Center for Biological Diversity v. England, 2003 U.S. App. LEXIS 1110 (D.C. Cir. 2003). These cases are inapposite,

because they both involve direct agency action alleged to be violative of the MBTA which was not reviewable under any statute other than the APA.

The purported claim under E.O. 13186 is equally without foundation. Section 5 of that Order is entitled "Application and Judicial Review" and states:

> This Order is intended only to improve the internal management of the Executive branch and does not create any right or benefit, substantive or procedural, separately enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

E.O. 13186, § 5(b). In any case, any alleged non-compliance with E.O. 13186 is not a justiciable claim because the implementation of an order that is derived from the constitutional power of the President and that has no direct legal consequences is not subject to judicial review. Franklin v. Massachusetts, 505 U.S. 788, 800-01 (1992); NRDC v. U.S. Dept. of State, 658 F. Supp. 2d 105 (D.D.C. 2009).

B. Any Claim That EPA Did Not Sufficiently Consider the MBTA or BGEPA When It Granted Liphatech's FIFRA Section 3 Registration Is Now Moot Given EPA's Decision on the WWF Petition

As established above, any claim by the Plaintiffs that EPA's issuance of the FIFRA Section 3 registration for Rozol Prairie Dog Bait was not consistent with the MBTA or the BGEPA would have to be evaluated in the context of the judicial review that is otherwise authorized by FIFRA. As Liphatech will show below, there has been no showing that registration of Rozol would result in a "take" of the sort prohibited by the MBTA, but it should not be necessary for the Court to reach this issue. Because EPA considered and responded to every argument made by the Plaintiffs in support of their MBTA and BGEPA claims in EPA's decision concerning the WWF Petition, these claims as presented here are moot and should be dismissed. *See* EPA Mem. at 40 (comparing MBTA and BGEPA arguments in Pl. Mem. with comments made by Plaintiffs and others concerning the WWF Petition). As noted above,

Plaintiffs will not be deprived of review on any proper claims under the MBTA or the BGEPA because the EPA decision concerning the WWF Petition is now reviewable in the Court of Appeals under FIFRA Section 16(b).

C. Even If There Is Some FIFRA Claim Concerning Compliance with MBTA or BGEPA That Is Not Moot, the Potential for Indirect Effects Following Use of Rozol Does Not Constitute a "Take" under These Statutes

If assuming for the sake of argument that the Plaintiffs can obtain judicial review of their claims concerning the MBTA and the BGEPA in the context of review under FIFRA, and that such claims are not moot, the claims are without merit. The potential effects of Rozol Prairie Dog Bait on those avian species covered by the MBTA and the BGEPA are not the sort of effects that would be construed as a "take" under these statutes.

The MBTA makes it unlawful to "pursue, hunt, take, capture, [or] kill" any migratory bird included in certain international conventions. 16 U.S.C. § 703(a). Implementing regulations define "take" as "to pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to pursue, hunt, shoot, wound, kill, trap, capture, or collect." 50 C.F.R. § 10.12. The BGEPA defines "take" to include "pursue, shoot, shoot at, poison, wound, kill, capture, trap, collect, molest or disturb." 16 U.S.C. § 668c.

These definitions clearly refer to direct actions against protected species. In Seattle Audubon Society v. Evans, 952 F.2d 297, 302 (9th Cir. 1991), the Court stated that the MBTA definitions describe "physical conduct of the sort engaged in by hunters and poachers, conduct which was undoubtedly a concern at the time of the statute's enactment in 1918." In Citizens Interested in Bull Run, 781 F. Supp 1502, 1510 (D. Or. 1991), the Court also held that the MBTA "was intended to apply to individual hunters and poachers." In Seattle Audubon, the

Court explained that the meaning of the word "take" is narrower than the same term as used in the ESA, and that this difference is both "distinct and purposeful." 952 F.2d at 303.

Several cases have held that the indirect effect on birds caused by habitat destruction is not a "take" under the MBTA. Seattle Audubon, 952 F.2d at 302-03; Citizens Interested, 781 F. Supp at 1509-10; Mahler v. U.S. Forest Service, 927 F. Supp. 1559, 1573-74 (S.D. In. 1996). The potential effects of use of Rozol Prairie Dog Bait on avian species are similarly indirect. Because Rozol must be applied six inches inside of burrows and the bait is inconspicuously colored, there is no reason to believe that lawful use of Rozol will lead to direct consumption of bait by any avian species.[10] AR 43 at 3. EPA analysts believe there is some potential for secondary toxicity if an avian raptor consumes prairie dog carcasses containing chlorophacinone,[11] but even if this type of event could occasionally occur, such indirect exposure would not constitute a "take" as that term is defined under either the MBTA or the BGEPA.

Even if the Plaintiffs' MBTA and BGEPA claims are deemed to be reviewable as part of the Court's FIFRA jurisdiction, and such claims are not moot, the Court should enter summary judgment against the Plaintiffs on these claims.

CONCLUSION

For all of the above reasons, the Court should deny Plaintiffs' Motion for Summary Judgment. The Court should also: (1) dismiss the Plaintiffs' procedural FIFRA claims as moot

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10 If Rozol is improperly applied by an individual user, and such a violation results in direct consumption of bait by avian species, this might result in criminal liability under the MBTA. *See* U.S. v. Corbin Farm Service, 444 F. Supp. 510 (E.D. Cal.), affirmed on other grounds 578 F.2d 259 (9th Cir. 1978) (poisoning resulting from misapplication of pesticides can be criminally sanctioned under the MBTA).

11 Liphatech believes that EPA's concerns about potential secondary toxicity are unwarranted, because avian secondary toxicity studies have not resulted in mortality. AR 43 at 2.

or enter summary judgment on these claims against the Plaintiffs; (2) dismiss the Plaintiffs' substantive FIFRA claims as moot; (3) dismiss the Plaintiffs' ESA claims as moot or enter summary judgment on these claims against the Plaintiffs; and (4) dismiss the Plaintiffs' claims under the MBTA, the BGEPA, and E.O. 13186 for lack of subject matter jurisdiction, or if the claims under the MBTA or the BGEPA are deemed reviewable under FIFRA, dismiss such claims as moot or enter summary judgment on these claims against the Plaintiffs.

DATED: December 15, 2010

Respectfully submitted,

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