IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BEYOND PESTICIDES/NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES et al.,	)	
Plaintiffs,	)	
v.	)	Case Number: 1:02CV02419 (RJL)
CHRISTINE T. WHITMAN, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,	)	
Defendant	)	

DEFENDANT'S MEMORANDUM IN OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

The principle purpose of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA" or "Act"), 7 U.S.C. §§ 136-136y., is to protect human health and the environment from unreasonable risks associated with pesticides. FIFRA does so by establishing a federal licensing scheme governing the sale, distribution and use of pesticides, and by requiring the Environmental Protection Agency ("EPA") to carefully balance the risks and benefits of each pesticide.[1/] FIFRA section 3 provides that, with minor exceptions not relevant here, "no person in any State may distribute or sell to any person any pesticide that is not registered" under FIFRA. 7 U.S.C. § 136a(a). And a pesticide may not be registered unless EPA concludes that it does not pose "any

[1/]A "pesticide" is defined, in part, as "any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest." 7 U.S.C. § 136(u). A pesticide registration is a license that allows the pesticide to be sold and distributed in accordance with certain terms and conditions that EPA determines are necessary to prevent unreasonable adverse effects to humans and the environment. See 7 U.S.C. § 136a(c), (d)(1).

unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. §§ 136a(b)(5), 136(bb). Currently, EPA is re-assessing pesticides that were registered before 1984 to determine whether they still meet these statutory standards.

Since as early as 1997, plaintiffs have been communicating with EPA to voice their objections to the use of the pesticide pentachlorophenol ("penta") as a wood preservative.[2/] Most recently, in December 2001, plaintiffs petitioned EPA to issue a notice of cancellation for all pesticides containing penta, and to suspend the registrations for such products pending a full review -- an action that would render the distribution, sale, or use of penta products (the vast majority of which are used to treat new utility poles) illegal throughout the United States. EPA responded to this petition in February 2002, explaining that EPA is already assessing the risks and benefits of penta as part of its ongoing reregistration review of all pesticides. See letter from Stephen Johnson (Feb. 5, 2002), attached as Exhibit 17 to plaintiffs' Memorandum. EPA therefore declined to either grant or deny plaintiffs' petition. Id.

A full ten months later, plaintiffs come to the Court seeking emergency relief. Plaintiffs do not, however, ask the Court to order EPA to act on their petition. Nor are plaintiffs merely seeking to maintain the status quo pending adjudication of the merits of their claim. Instead, plaintiffs ask the Court to order EPA immediately to (1) issue a notice of intent to cancel the

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[2/]Penta is a wood preservative used almost exclusively for the treatment of utility poles. Declaration of Jack E. Housenger ("Housenger Decl."), ¶ 14. Plaintiffs also challenge the use of chromated copper arsenate ("CCA") and creosote as wood preservatives. Plaintiffs' Complaint For Declaratory And Injunctive Relief ("Complaint"), ¶ 1. Plaintiffs' claims regarding CCA and creosote are not the subject of plaintiffs' motion for a preliminary injunction. Plaintiffs' Memorandum Of Points And Authorities In Support Of Motion For Preliminary Injunction ("Pl. Mem."), p. 1 n.1.

pesticide registrations for all products containing penta for use as wood preservatives, and (2) issue an emergency order immediately suspending the pesticide registrations for all such products. In other words, plaintiffs ask the Court, rather than EPA, to determine whether penta "generally causes unreasonable adverse effects on the environment," whether those effects are significant enough to constitute an "imminent hazard" to human health, and whether that hazard is grave enough that it constitutes an "emergency" within the meaning of FIFRA. See 7 U.S.C. § 136d(b), (c). The effect of plaintiffs' requested order would be that within the time period set by the Court, penta products could no longer be distributed, used, or sold anywhere within the United States.

Plaintiffs' requested relief would be extraordinary under any circumstances. It becomes even more so when EPA's pesticide reregistration review is taken into account. EPA has been working to fulfill a Congressional mandate to re-examine pesticide registrations and re-register many pesticides – a mandate that has required the examination of thousands of registered pesticide products. With regard to its re-assessment of penta in particular, EPA has nearly completed the first step in this process (issuance of a preliminary risk assessment) and is now beginning to examine the other side of the equation, i.e., the current benefits derived from using penta. Once the preliminary risk assessment is issued, based upon EPA's past experience, it is likely to take approximately 6 to 8 months to complete a Registration Eligibility Decision ("RED"). See Declaration of Jack Housenger ("Housenger Decl.), ¶ 25. Depending on various contingencies, however, such as data or analyses received in public comments, the development of complicated new scientific issues, and the need to address difficult risk mitigation and implementation issues, it could take as long as 3 years to complete a RED.

Plaintiffs, however, ask the Court to decree that penta should be immediately pulled from the market (at a monetary cost, public burden and impact on human health that neither plaintiffs nor EPA can now predict), even though EPA has not yet completed its review. Plaintiffs do not even attempt to assess the real potential impact of an immediate suspension of penta products; rather, plaintiffs rely solely on one-sided documents that, in plaintiffs' view, prove conclusively that the alternatives they favor are adequate and readily available substitutes.

Plaintiffs have utterly failed to meet the rigorous standards applicable to a request for a mandatory preliminary injunction. Initially, plaintiffs are unlikely to succeed on the merits of their quest to substitute the Court's judgment for EPA's. The Court does not have jurisdiction to grant the relief that plaintiffs seek. Plaintiffs are not entitled to judicial review under FIFRA unless and until EPA has taken a final agency action refusing to grant their cancellation petition. There is no dispute that EPA has neither granted nor denied plaintiffs' petition. Yet, even assuming plaintiffs could establish that EPA's failure to act on the petition is unreasonable delay under the APA as they allege in their complaint, they have not sought preliminary relief on those grounds. Moreover, the most that plaintiffs could hope for if they succeed on an unreasonable delay claim would be an order directing EPA to grant or deny the petition, not an order requiring EPA to reach the substantive result favored by plaintiffs.

With regard to the merits of plaintiffs' claim that EPA is required to pull penta from the market based upon the "findings" made in a three year old draft preliminary risk assessment, plaintiffs have failed to take account of several critical factors. First, the 1999 draft preliminary risk assessment is not EPA's final word on the risks of penta; the risk review is still ongoing. Second, plaintiffs do not offer evidence showing what can realistically be expected to replace

penta in the marketplace and whether that replacement will be safer than penta. And third, plaintiffs offer nothing other than their own opinion, and that of the manufacturers of their preferred alternatives, to support their claim that there are other products that could readily substitute for penta-treated wood, and that therefore the risks of penta necessarily outweigh its benefits. Thus, plaintiffs cannot show a likelihood of success on the merits.

Even more significant with respect to plaintiffs' request for emergency relief is that plaintiffs cannot show why, after years of working with EPA, and nine months after EPA's statement that it was neither granting nor denying their petition, their objections to the continued use of penta have suddenly become so urgent that immediate action is required to prevent an irreparable injury. Finally, plaintiffs can neither overcome the impact on EPA's pesticide reregistration process threatened by a sudden re-ordering of priorities and diversion of resources to examine penta ahead of everything else, nor ignore the possibility of harm to the public if the entire utility industry were deprived of penta-treated wooden poles and were forced to switch to other products (which may or may not be safer, and which may or may not pose risks other than those posed by penta).

EPA has made significant progress in its pesticide reregistration program, but is still only partway through its evaluation of the risks and benefits of penta. Plantiffs offer no compelling justification for disrupting that process, overriding EPA's judgment, and taking a step that may (or may not) pose unanticipated risks. Plaintiffs' motion should therefore be denied.

I. BACKGROUND

A. STATUTORY BACKGROUND.

1. Pesticide Registration.

Under FIFRA, EPA registers a pesticide only after conducting extensive scientific review of the risks and benefits of that pesticide to determine whether the use of the pesticide causes "unreasonable adverse effects" to human health or the environment. "Unreasonable adverse effects" in relevant part means "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." 7 U.S.C. § 136(bb).

The process for registering a pesticide is set forth in both FIFRA and EPA's regulations, which establish basic application procedures and detailed data submission requirements. See 7 U.S.C. § 136a; 40 C.F.R. §§ 152.1, 158.20. Once EPA registers a pesticide, EPA may require additional data later, "if [EPA] determines that additional data are required to maintain in effect an existing registration of a pesticide." 7 U.S.C. § 136a(c)(2)(B)(i). EPA also is authorized to suspend or cancel pesticide registrations, or issue notices of intent to suspend or cancel registrations. 7 U.S.C. §§ 136a(c)(2)(B)(iv), 136d.

2. Cancellation And Suspension of Registrations.

EPA can cancel a pesticide registration if that registration is not in compliance with FIFRA requirements. 7 U.S.C. § 136d(b). If it appears to EPA that a pesticide does not comply with FIFRA or, when used in accord with widespread practices, "generally causes unreasonable adverse effects on the environment," EPA may issue a notice of its intent to either (1) cancel the pesticide's registration or change its classification or (2) hold a hearing to determine whether the registration

should be canceled. Id. Before issuing such a notice, EPA must seek the advice of the Secretary of Agriculture and the EPA Science Advisory Panel through a process set forth in the statute. Id. EPA may then issue the notice to the registrant and to the public.[3] If EPA issues a notice of intent to cancel the registration, rather than a notice of intent to hold a hearing, cancellation becomes final and effective 30 days after (1) the registrant has received notice and (2) the notice has been published, unless the registrant corrects the defects or "a person adversely affected by the notice" requests a hearing. Id. If a hearing is requested, the final decision on cancellation will be issued after completion of the hearing in accord with EPA's regulations. 40 C.F.R. Part 164.

FIFRA also provides the Administrator with the authority to immediately suspend the registration of a pesticide if necessary to prevent an "imminent hazard."[4] 7 U.S.C. § 136d(c). The Administrator is required to issue a notice of intent to cancel a registration prior to or simultaneously with the suspension. Id. The Administrator is required to provide notice to affected registrants prior to issuing a suspension order, and registrants are entitled to request an expedited hearing during which the order will not be in effect. Id. § 136d(c)(1), (2). Finally, the Administrator can issue an emergency suspension order without issuing a notice of intent to cancel or notifying the affected registrants in emergency situations that do "not permit the Administrator to hold a hearing before suspending." Id. § 136d(c)(3). After an emergency suspension order, the

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[3]FIFRA defines a "registrant" as "a person who has registered any pesticide pursuant to the provisions of this [Act]." 7 U.S.C. § 136(y).

[4]FIFRA defines "imminent hazard" as "a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary of the Interior pursuant to the Endangered Species Act of 1973." 7 U.S.C. § 136(l).

registrants have a right to request a hearing. The emergency order remains in effect during the pendency of a hearing on the order. In addition, the Administrator is required to then issue a notice of intent to cancel within 90 days after the issuance of the emergency suspension order. If the emergency order is not rescinded, it remains in effect through any subsequent cancellation proceedings. Id.

3. Pesticide Reregistration

Prior to the 1988 amendments to FIFRA, EPA reevaluated the risks and benefits of currently registered pesticides through the Rebuttable Presumption Against Review (RPAR) process (now called the Special Review process). EPA created RPAR as an administrative process to evaluate these risks and an benefits without having to first issue a notice of intent to cancel. Housenger Decl. ¶ 4. EPA's current procedures for the Special Review process are codified at 40 C.F.R. part 154, and include specific opportunities for involvement of both registrants and the public. See 40 C.F.R. part 154.21, 154.26, & 154.27.

In 1988, Congress created the reregistration process now embodied in FIFRA Section 4. Section 4 requires that EPA re-examine existing pesticide registrations, and includes a schedule for "reregistration" of many pesticides. 7 U.S.C. § 136a-1. Under this section, EPA is required to reregister any pesticide that was first registered before November 1, 1984.[5/] Id. § 136a-1(a). The reregistration process originally covered approximately 600 distinct active ingredients that are incorporated into thousands of pesticide products. This reregistration is to occur in five phases

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[5/]Exceptions to this requirement are pesticides for which EPA, between November 1, 1984 and the effective date of the registration, had determined (1) that there were no outstanding data requirements, and (2) the requirements of FIFRA § 3(c)(5), 7 U.S.C. 136a(c)(5) had been met. See 7 U.S.C. § 136a-1(a).

with deadlines for each of the phases. 7 U.S.C. § 136a-1(b)-(g); see also Declaration of Jack Housenger ("Housenger Decl."), ¶ 7. At the conclusion of this five-phase process, EPA determines whether reregistration is appropriate for each registered pesticide.

To help fulfill its reregistration mandate, EPA has elected to create a non-mandatory, multi-step procedure granting considerable public participation opportunities. Housenger Decl. ¶¶ 9-13. The first several steps, including the preparation of preliminary and revised risk assessments, lead up to "Reregistration Eligibility Decisions," or "REDs." Id. REDs embody EPA's determinations of whether pesticides containing particular active ingredients are eligible for reregistration under FIFRA section 4(g)(2)(A), 7 U.S.C. § 136a-1(g)(2)(A); see also Housenger Decl. ¶ 7. If EPA determines that a pesticide is eligible for reregistration, EPA can issue a data call-in for product specific data under FIFRA section 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(B). 7 U.S.C. § 136a-1(g)(2)(B). After reviewing the product-specific data, EPA must determine if the product meets the requirements for reregistration. 7 U.S.C. § 136a-1(g)(2)(C). If EPA determines that a pesticide is not eligible for reregistration, this determination is not itself a final agency action. In such cases, Section 4 directs EPA to take "appropriate regulatory action." 7 U.S.C. § 136a(1)(g)(2)(D).

B. STATEMENT OF FACTS.

1. The Pesticide Reregistration Program.

a. The reregistration program in general.

In order to evaluate pesticides under the reregistration program, EPA first collects data regarding individual pesticide active ingredients and thoroughly evaluates the potential risks of those pesticides. Housenger Decl. ¶ 6. EPA then proceeds to evaluate the countervailing benefits

of a given pesticide, an evaluation that includes consideration of alternatives to that pesticide and the impacts that could result from use of those alternatives. Id.; see also Declaration of Denise Keehner ("Keehner Decl.") ¶¶ 2-3. The reregistration process includes opportunities for public comment and participation. Housenger Decl. ¶¶ 9-13; see also Keehner Decl. ¶ 4. Once both the internal process and the public reviews are complete, EPA can balance risks against the benefits to determine whether the pesticide meets FIFRA registration standards. Housenger Decl. ¶¶ 6-7; Keehner Decl. ¶¶ 2-3. Penta is one of the pesticides undergoing the reregistration process. Housenger Decl. ¶ 18.

b. EPA's review of penta.

Penta has been a registered pesticide since 1948. Housenger Decl. ¶ 14. EPA first began re-examining the risks associated with exposure to penta in 1978 pursuant to the Rebuttable Presumption Against Registration ("RPAR") process. Housenger Decl. ¶ 15. As part of this process, EPA conducted a detailed assessment of the risks and benefits of penta (along with CCA and creosote, two other wood preservative pesticides) and issued preliminary findings in 1981 that the risks of all three were such that regulatory restrictions were necessary in order to maintain their registrations. Housenger Decl. ¶ 15. The RPAR process with regard to penta culminated in 1984, when EPA issued a Notice of Intent to cancel the registration of all three wood preservative pesticides. Housenger Decl. ¶ 16. This Notice in turn led to a negotiated settlement with penta registrants (as opposed to a lengthy and costly hearing), resulting in labeling and use restrictions on penta to reduce the risks to acceptable levels. Housenger Decl. ¶ 17.

In 1997, EPA began a reregistration review of penta. Hounsenger Decl. ¶¶ 6, 18. As in the prior RPAR review, EPA has been reviewing penta, creosote, and CCA together, in order to

assure that EPA's ultimate decision will take into account the potential impacts if any of the three wood preservative pesticides is substituted for another. Housenger Decl. ¶ 18; see also id. ¶ 15. In 1999, as part of this process, EPA developed a draft preliminary risk assessment for penta; although this draft chapter was released to penta registrants and, later, to the public, for review and comment, it was never intended to be the final risk assessment for penta. Housenger Decl. ¶ 19. On November 27, 2002, the Antimicrobials Division of EPA's Office of Pesticide Programs completed a new draft preliminary risk assessment for penta. Housenger Decl. ¶ 22. This draft preliminary assessment is currently undergoing an internal quality control review; once that review is complete, and the assessment has been subject to comment from registrants and the public, it will be revised as appropriate and used by EPA to complete the RED for penta and the other two wood preservatives. Housenger Decl. ¶¶ 22-23.

EPA has just begun its re-examination of the other side of the reregistration equation, i.e., the benefits of using penta. Keehner Decl. ¶ 4. Typically, benefits assessments are not performed until after risk assessments are complete and have been released for public comment. Id. ¶ 3. This enables the benefits assessment to take into account the impact of risk mitigation measures identified in the course of the risk management phase of the reregistration process. Id. ¶ 3. Like the draft preliminary risk assessment, the benefits assessment will be made available for public comment. Id. ¶ 4. Critical questions remain to be examined during the benefits assessment process for penta, including (1) the extent to which any one of three main wood preservative pesticides can be substituted for another, and the consequences of such a shift; (2) the availability and cost-effectiveness of other potential wood preservative pesticides; (3) the availability and cost-effectiveness of non-pesticide-treated materials; and (4) the possible economic and social impacts

of switching to other pesticides or non-pesticide-treated materials. Answering these questions will require EPA to consider a host of subsidiary issues. Keehner Decl. ¶¶ 6, 8. Only when this process is complete will EPA be in a position to determine whether or not the risks of penta outweigh its benefits and, accordingly, whether penta is eligible for reregistration under FIFRA's unreasonable risk standard. Id. ¶ 3.

c. Public participation in EPA's review of penta.

Ever since the start of the reregistration process for penta and related wood preservatives, EPA has met and communicated with various interested parties (including plaintiffs) to discuss the progress of the review and to receive information that may bear on that review. Housenger Decl. ¶ 21; see also Keehner Decl. ¶ 6(c). Plaintiffs' contacts with EPA regarding their objections to penta are detailed in the exhibits to Plaintiffs' Memorandum. Moreover, as discussed above, there have been, and will be further, opportunities for public comment on both the risks and benefits assessments that EPA will use to develop a RED for penta. See Housenger Decl. ¶¶ 9-13, 23-24; Keehner Decl. ¶ 4.

II. STANDARD OF REVIEW

Plaintiffs seek an injunction directing EPA to: (1) issue a notice of intent to cancel the pesticide registrations for all products containing penta for use as wood preservatives, and (2) issue an emergency order suspending the pesticide registrations for all products containing penta for use as wood preservatives. As the Supreme Court has noted, typically "[t]he purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." University of Texas v. Camenisch, 451 U.S. 390, 395 (1981). To be entitled to the extraordinary relief of a preliminary injunction, plaintiffs would typically need to show "1) a

substantial likelihood of success on the merits, 2) that [they] would suffer irreparable injury if the injunction is not granted, 3) that an injunction would not substantially injure other interested parties, and 4) that the public interest would be furthered by the injunction." Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (citation omitted).

Plaintiffs, however, seek more than a preliminary "prohibitive" order enjoining EPA from taking a particular action to preserve the status quo – they seek a "mandatory preliminary injunction" that would order EPA to take affirmative action to *change* the status quo for penta pesticide registrants, marketers and users by issuing notices of intent to cancel the pesticide registrations for penta's use as a wood preservative and issuing emergency suspension orders. A request for injunction that seeks to change the status quo is a request for mandatory injunction. See Veitch v. Danzig, 135 F. Supp.2d 32, 35 n.2 (D.D.C. 2001). In other words, a party seeking a mandatory injunction seeks to require the defendant to take "affirmative steps" to reverse the current state of affairs. Id. at 35 (former Navy chaplain sought to have Navy affirmatively reverse his separation from the Navy and reinstate him to active duty).

A party seeking a mandatory preliminary injunction is subject to an even higher standard than one seeking a prohibitory preliminary injunction designed to maintain the status quo. See Veitch, 135 F. Supp. 2d at 35 (plaintiff seeking mandatory injunction "must meet a higher standard" than if plaintiff was seeking typical prohibitory injunction). Specifically, plaintiffs must show that they "clearly" are entitled to relief or that "extreme or very serious damage will result from a denial of the injunction." Id. at 35 n.2 (citations omitted); see also Columbia Hosp. for Women Found., Inc. v. Bank of Tokyo-Mitsubishi, Ltd., 15 F. Supp. 2d 1, 4 (D.D.C. 1997) (the law and facts must "clearly favor" the party moving for a mandatory injunction) (citation omitted),

aff'd, 159 F.3d 636 (D.C. Cir. 1998) The D.C. Circuit therefore has emphasized that "[t]he power to issue a preliminary injunction, especially a mandatory one, should be 'sparingly exercised.'" Dorfmann v. Boozer, 414 F.2d 1168, 1173 (D.C. Cir. 1969) (citation omitted); see also Columbia Hosp., 15 F. Supp. 2d at 4 (courts must be "extremely cautious" about granting preliminary relief that goes beyond maintaining the status quo).[6/]

This high standard is even further elevated when the target of the mandatory preliminary injunction is an agency of the Executive Branch. In this Circuit, "[a]n action purportedly requesting a mandatory injunction against a federal official is analyzed as one requesting mandamus." National Wildlife Fed'n v. United States, 626 F.2d 917, 918 n.1 (D.C. Cir. 1980). The D.C. Circuit has emphasized that mandamus relief "is an extraordinary remedy [and] we require similarly extraordinary circumstances to be present before we will interfere with an ongoing agency process." In re United Mine Workers of America Int'l Union, 190 F.3d 545, 549 (D.C. Cir. 1999) (quoting Community Nutrition Inst. v. Young, 773 F.2d 1356, 1361 (D.C. Cir. 1985)).

[6/]Plaintiffs suggest that a weak showing on any one of the factors applicable to a request for a prohibitory preliminary injuction may be offset by a stronger showing on some other factor. Pl. Mem. p.18. Even if this might be true in the ordinary case, as the court recognized in Columbia Hospital, where a party seeks a mandatory injunction it is inappropriate to "dilute the burden that [plaintiffs] must bear in clearly demonstrating that the law and facts support their request." Columbia Hospital For Women Foundation Inc. v. Bank of Tokyo-Mitsubishi Ltd., 15 F. Supp. 2d 1, 4 (D.D.C. 1997). The court characterized as "myopic" plaintiffs' suggestion that if they made a strong showing on other factors, the court could overlook a weak showing on the merits. Id. While defendants do not agree that plaintiffs in this matter have made an adequate showing on any of the factors governing a request for a preliminary injunction, their unusually weak showing with regard to the merits of their claim counsels strongly against granting their motion. Id. (noting that as a rule, when mandatory preliminary injunction is requested, court "should deny such relief unless the facts and law clearly favor the moving party") (citation omitted; emphasis in original).

Plaintiffs try to circumvent this extremely high burden by arguing that they are not seeking a mandatory injunction because they seek to "*preserve* the status quo by maintaining the existing amount of penta and penta-treated wood in the environment rather than changing the status quo by adding to it." Pl. Mem. p. 25 n.52 (emphasis in original). Plaintiffs' argument defies reason. First, Plaintiffs acknowledge elsewhere in their memorandum that the relief they seek would alter the status quo. In attempting to downplay the impact of a preliminary injuction requiring the suspension of penta's registration, plaintiffs argue that if ultimately they "are not successful on the merits, the status quo permitting the use of penta can be easily restored." Pl. Mem. at 26 (emphasis added). If issuance of a preliminary injunction would not change the status quo (as plaintiffs claim on page 25) then it makes no sense to state that the "status quo permitting the use of penta can be easily restored" (as plaintiffs claim on page 26).

Second, plaintiffs incorrectly focus on the presence of penta in the environment as the measure of the status quo. The proper focus is on whether the relative position of the parties will be changed by issuance of the preliminary injunction. See University of Texas v. Camenisch, 451 U.S. at 395 ("[t]he purpose of a preliminary injunction is merely to preserve the relative position of the parties until a trial on the merits can be held"); SCFC ILC, Inc. v. Visa USA, Inc., 936 F.2d 1096, 1100 (10th Cir. 1991) (status quo is defined by "the *reality* of the existing status and relationships between the parties") (italics in original). Plaintiffs ignore the fact that EPA's current regulation of penta, and the current rights of penta registrants and users, will not be preserved by an injunction. Instead, EPA will be required to undertake extensive cancellation and suspension processes that will immediately halt the nationwide sale, distribution, and use of penta as a wood preservative by any person. Because an injunction would require EPA to take affirmative action to

change the current status of EPA's nationwide registration program for penta, which in turn would change the current status of all penta registrants and users, plaintiffs' requested injunctive relief cannot be viewed as anything less than a mandatory injunction that would profoundly alter the status quo.

III. ARGUMENT

A. PLAINTIFFS CANNOT SHOW A LIKELIHOOD OF SUCCESS ON THE MERITS.

1. The Court Lacks Jurisdiction To Grant The Relief Requested By Plaintiffs.

In their complaint, plaintiffs assert three possible bases for jurisdiction: (1) Section 10(a) of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551-559, 701-706, which provides for judicial review of agency actions; (2) Section 10(e) of the APA, which allows a reviewing court to "compel agency action unlawfully withheld or unreasonably delayed;" and (3) Section 16(a) of FIFRA, which grants district courts jurisdiction to review "the refusal of [EPA] to cancel or suspend a registration . . . and other final actions of [EPA] not committed to the discretion of [EPA] by law." Complaint ¶ 8; 5 U.S.C. § 706(1); 7 U.S.C. § 136n(a). [7] None of these provisions gives the Court jurisdiction to grant the relief requested by plaintiffs in their motion for preliminary injunction.

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[7] Plaintiffs also cite to 28 U.S.C. § 1331 (the general federal question jurisdiction statute) and 28 U.S.C. § 2201 (the Declaratory Judgment Act). It is well settled that neither of these statutes constitute a waiver of sovereign immunity. See, e.g., Garcia v. United States, 666 F.2d 960, 966 (5th Cir. Unit B 1982) (28 U.S.C § 1331 does not waive the United States' immunity); Amalgamated Sugar Co. v. Bergland, 664 F.2d 818, 822 (10th Cir. 1981) (28 U.S.C. § 2201 does not waive the United States' immunity); Benvenuti v. Department of Defense, 587 F. Supp. 348, 352 (D.D.C. 1984) (neither 28 U.S.C § 1331 nor 28 U.S.C. § 2201 waives the United States' immunity).

Because there has not yet been any final agency action by EPA with regard to plaintiffs' petitions or penta's registration, there is no final agency action to review under either the APA or FIFRA. Critically, plaintiffs do not seek any preliminary relief on their "unreasonable delay" claim under Section 706(1) – they are not asking the Court simply to order EPA to act on their petition one way or the other. Instead, plaintiffs ask the Court to proceed directly to ordering EPA to immediately cancel and suspend penta's registration. Even if FIFRA or the APA did provide for judicial review at this stage, plaintiffs' remedy would be limited to an order requiring EPA to act on plaintiffs' petition – relief that plaintiffs have not requested. Plaintiffs' Motion for Preliminary Injunction should therefore be denied.

a. This Court Lacks Jurisdiction Because EPA Has Not Taken Any Final Agency Action.

(1) Plaintiffs bear the burden of establishing an applicable waiver of sovereign immunity.

Federal courts are courts of limited jurisdiction that may exercise only those powers authorized by Constitution and statute. Kokkonen v. Guardian Life Ins. Co. of America, 511 U.S. 375, 377 (1994). Therefore, "[i]t is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." Kokkonen, 511 U.S. at 377 (citations omitted). A party seeking to sue the United States bears the additional burden of demonstrating that a specific statutory provision waives the government's sovereign immunity from suit. United States v. Sherwood, 312 U.S. 584, 586 (1941). Unless Congress has consented to a cause of action against the United States, there is no jurisdiction in any court to entertain such suit. Id. at 587-88. This principle extends to agencies as well, which are immune from suit absent a showing of a waiver of sovereign immunity. See FDIC v. Meyer,

510 U.S. 471, 475 (1994).

Only Congress can waive the United States' sovereign immunity. A waiver of sovereign immunity "must be unequivocally expressed in statutory text and will not be implied." Lane v. Pena, 518 U.S. 187, 192 (1996) (citations omitted). Furthermore, waivers of sovereign immunity are "construed strictly in favor of the sovereign." United States Dep't of Energy v. Ohio, 503 U.S. 607, 614 (1992) (addressing waivers of sovereign immunity in federal environmental statutes).

(2) FIFRA Section 16 allows suits against EPA only after challenges a final agency action.

The judicial review provisions of FIFRA are set forth in section 16, 7 U.S.C. § 136n. Section 16(a) provides:

> Except as otherwise provided in this subchapter, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States
> .

7 U.S.C. § 136n(a). Section 16(a) is the exclusive means of obtaining judicial review in the district courts of EPA actions under FIFRA.[8/] Defenders of Wildlife v. EPA, 882 F.2d 1294, 1302 (8th Cir. 1989) ("Although the APA may state the scope of review, FIFRA still provides the mechanism for obtaining judicial review. Thus, the APA does not operate separately from FIFRA, but instead as a part of FIFRA." (citations omitted)). FIFRA section 16(a) waives sovereign immunity and provides a basis for subject matter jurisdiction only where EPA has taken some final agency action. See Syngenta Crop Protection Inc. v. EPA, 202 F. Supp. 2d 437, 446-47 (M.D.N.C.

[8/]Congress at one time considered a citizen suit provision, but rejected it in favor of the limited waiver of sovereign immunity contained in FIFRA § 16(a). See S. Rep. No. 92-970, 92nd Cong., 2d Sess. 4 (1972), 1972 USCCAN 4092, 4125 (describing a proposal for a citizen suit provision modeled after the Clean Air Act).

2002) (finding no jurisdiction under Section 16(a) of FIFRA where there had been no final agency action). As with all waivers of sovereign immunity, the language of Section 16(a) must be strictly construed in favor of the federal government. See United States v. Nordic Village Inc., 503 U.S. 30, 33 (1992).

Section 16(a) lists the instances in which a district court has jurisdiction: refusal of EPA to cancel a registration not following a hearing; refusal of EPA to suspend a registration not following a hearing; refusal of EPA to change a classification not following a hearing; and "other final actions" of EPA. 7 U.S.C. § 136n(a). The phrase "and other final actions of the Administrator" is important because canons of statutory construction require courts to read statutory provisions in their entirety and words within their context. Deal v. United States, 508 U.S. 129, 131 (1993). Reading the words of Section 16(a) in context, the phrase "and other final actions of the Administrator" indicates that the first three categories for which the district courts have jurisdiction must also be final agency actions.

Section 16(a) thus simply does not provide for the review of agency inaction on a petition for cancellation. Cf. EDF v. Costle, 657 F.2d 275, 283 (D.C. Cir. 1981) (under APA, challenge to agency inaction is an unreasonable delay claim under section 706(1), not a challenge to final action, as authorized by § 706(2)).

(3) The cases cited by plaintiffs to support their claim of jurisdiction were decided under a substantially different version of FIFRA.

Plaintiffs cite three cases for the propositions that "EPA's failure to cancel or suspend a pesticide may be challenged in a court even when EPA asserts that it still has the matter under consideration" and that "short-term inaction is considered tantamount to denial of a request to

suspend a pesticide's registration." Pl. Mem. at 12 (citing EDF v. Hardin, 428 F.2d 1093 (D.C. Cir. 1970); EDF v. Ruckelshaus, 439 F.2d 584 (D.C. Cir. 1971); and EDF v. EPA, 465 F.2d 528 (D.C. Cir. 1972)). First, the statutory provision interpreted by the D.C. Circuit in the EDF cases has since been replaced with the substantially different judicial review provision now found in Section 16(a).[9] Thus, by definition, these cases could not have addressed the scope of Section 16(a).

Moreover, the D.C. Circuit's discussion of finality in the EDF cases must be viewed against the backdrop of the then-existing version of FIFRA. At the time, there was no specific process in FIFRA whereby EPA could re-assess a registered pesticide. See infra at 24-25. It was thus logical for the court to conclude that inaction on a cancellation or suspension petition effectively precluded consideration of the substantive concerns raised in that petition, and therefore constituted final agency action. See Hardin, 428 F.2d at 1099.

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[9]In EDF v. Hardin, the D.C. Circuit found jurisdiction absent a final agency action based upon language that is no longer in FIFRA. The court was asked to review the propriety of EPA's delay in responding to petitioner's request for a suspension of registrations of DDT. Hardin, 428 F.2d at 1095-1096. At that time, the judicial review provision of FIFRA read as follows:

> In a case of actual controversy as to the validity of any order under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeal for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

7 U.S.C. § 135b(d) (1964) (repealed). The Court cited this provision in its decision, noting that "FIFRA provides for judicial review 'in a case of actual controversy as to the validity of any order under this section.'" Hardin, 428 F.2d at 1098, n.21. Furthermore, the Court's reasoning was tied to the language of the review provision, holding that "the controversy over interim relief is ripe for judicial resolution." Id. at 1099 (emphasis added). The court found that although EPA had not taken final action on petitioner's request, the "controversy" surrounding the request was sufficiently ripe to confer jurisdiction.

By contrast, FIFRA now provides a detailed and specific process whereby EPA is required to re-assess the risks and benefits of registered pesticides. As discussed above, see supra at 10-12, penta is undergoing just such a re-assessment. Thus, contrary to plaintiffs' assertions, a failure to act on a cancellation or suspension petition for penta is no longer tantamount to denial of that petition, and no longer can be considered final agency action.

(4) There has been no final agency action.

In this case, EPA has taken no final agency action with regard to Beyond Pesticides's petition to cancel the current registrations for penta. There has been no definitive ruling by which any rights or obligations have been determined or from which legal consequences will flow. See Bennett v. Spear, 520 U.S. 154, 177-78 (1997) (citations omitted); see also DRG Funding Corp. v. Secretary of Housing & Urban Dev., 76 F.3d 1212, 1214 (D.C. Cir. 1996) (final agency action occurs when agency has "completed its decisionmaking process" and "arrived at a definitive position"). In a February 2002 letter from Stephen L. Johnson, Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances (OPPTS), to Jay Feldman, Executive Director of Beyond Pesticides, EPA stated that it was making an "interim reply" to Beyond Pesticides that constituted "neither a denial nor an acceptance of [the] petition." See Pl. Exh. 17. Furthermore, the letter indicated that pentachlorophenol was "currently undergoing reregistration review," a process that required a "credible and reliable assessment" of the chemical.
Mr. Johnson's letter is indisputable evidence that the Agency has not taken any final agency action with regard to Beyond Pesticides's petition.

EPA's response to Plaintiffs' petition does not necessarily leave plaintiffs stranded in administrative limbo. Plaintiffs have, however, opted not to seek preliminary relief under the APA,

and therefore this Court lacks jurisdiction to grant the relief plaintiffs request.

b. Even assuming *arguendo* that jurisdiction exists, the EDF cases cited by plaintiffs indicate that the sole remedy available is a remand to EPA for a final decision on plaintiffs' petition.

EDF v. Hardin is the first case cited by plaintiffs in which the court was asked to review a petition for suspension before the Agency had responded to the petition. In that case, in the face of a petition to cancel all registrations of DDT, the Secretary issued notices of intent to cancel some uses of DDT, took comment on whether to issue notices of intent to cancel other uses of DDT, and did not respond to petitioners' request for an emergency suspension of the registration. Hardin, 428 F.2d at 1095-1096. Although the Court found the controversy ripe for review, it did not opine on the legality of the Department's inaction. Instead, the Court noted that "meaningful appellate review" "is impossible in the absence of any record of administrative action" and therefore remanded the case to the Secretary. Id. at 1099. In remanding, the Court specifically gave the Department a chance to make a "fresh determination" on the question of whether suspension or notices of intent to cancel were appropriate, thereby allowing the Department to decide either to grant or deny the initial petition. Id. at 1100. The D.C. Circuit took a similar approach one year later in EDF v. Ruckelshaus on the issue of emergency suspensions, remanding the issue to EPA once again for a "fresh determination" because there was no administrative record for the court to review. 439 F.2d at 596. These cases indicate that an administrative record is essential for meaningful judicial review, and that the proper remedy in a situation where the Agency has not formally decided an issue is to remand that issue to the Agency for a decision.

The only instance cited by plaintiffs where a court has actually issued an injunction to EPA requiring a specific substantive result under FIFRA is factually distinguishable from the case before

this Court. In EDF v. Ruckelshaus, the D.C. Circuit did order the EPA to issue notices of intent to cancel the remaining registrations of DDT. 439 F.2d at 595. In that case the Court was able to point to specific final statements made by the Agency in a final document entitled "Statement of Reasons Underlying the Decisions on Behalf of the Secretary with respect to the Registrations of Products Containing DDT." Id. at 594, n.38. Those statements, in the Court's opinion, satisfied the statutory standard for when a notice of intent to cancel is required. Id. at 595. No such final statements exist in this case. Rather, plaintiffs' motion relies upon a draft version of the science chapter of a forthcoming draft risk assessment of penta. **Cite their memo**. Since the draft preliminary risk assessment was released for public comment, it has undergone changes, most notably inclusion of a worker safety study and consideration of contaminants. See Housenger Decl. ¶ 22. Further, once released, the draft risk assessment itself will be subject to public comment and review. Id. ¶ 22. The interim statements cited by plaintiffs are clearly distinguishable from the statements made by the Administrator in a final document generated for the express purpose of explaining the Agency's actions. Moreover, as explained in more detail below, those statements do not reflect any consideration of the "economic, social, and environmental . . . benefits of the use" of penta. See 7 U.S.C. § 136(bb).

2. Plaintiffs Are Unlikely To Succeed On The Substantive Merits Of Their Claim.

a. Plaintiffs are unlikely to succeed on the merits of their claim under FIFRA.

Plaintiffs argue that because EPA has allegedly made "findings" concerning the risks posed by penta, EPA is automatically required to issue notices of cancellation and to issue an emergency suspension order. Plaintiffs rely heavily on the EDF trio of cases to support this claim. However,

the significant changes in FIFRA since those cases were decided and the factual distinctions between those cases and this matter render the cases unpersuasive in this context.

(1) FIFRA has changed significantly since the EDF cases were decided.

Since the D.C. Circuit decided the cases cited by plaintiffs, Congress has made three significant amendment to FIFRA. First, Congress "completely revised" the Act in 1972. Second, in 1988, Congress amended FIFRA to provide for the reregistration of pesticides registered prior to 1984. 7 U.S.C. § 136a-1. Finally, in 1996, Congress passed the Food Quality Protection Act (FQPA), which required the Agency to reassess pesticide tolerances. These later two amendments have resulted in Congressionally-mandated processes for reviewing the risks and benefits of currently registered pesticides, processes that were noticeably absent from the statutory scheme before the Court in the early 1970s. Prior to 1964, FIFRA included a "protest registration" scheme that required the government to register a pesticide even in those situations where the registration application did not conform with FIFRA's requirements. FIFRA § 4(c); see Ruckelshaus, 439 F.2d at 593. In 1964 Congress passed amendments eliminating this approach in favor of the current approach, which places the burden of demonstrating safety and compliance with the Act with the registrant. When the cases cited by plaintiffs were decided, FIFRA contained no specific mechanism for reregistration or post-registration review. The D.C. Circuit noted that FIFRA had granted the public "a role in deciding important questions of public policy" and that the only way to give the public a chance to perform its role was for the Administrator to issue notices of intent to cancel in order to "commence the administrative process." Ruckelshaus, 439 F.2d at 594-595.

Notices of intent to cancel and emergency suspensions are no longer the sole avenue EPA can take to commence public proceedings to examine currently-registered products that pose a substantial question of safety. In fact, EPA is now required to re-examine many registered pesticides on its own. In 1988 and again in 1996 Congress created new, detailed processes for reevaluating the safety and benefits of a registered pesticide and mandated that the Agency use those processes. Under both of these processes EPA provides opportunities for public involvement, such as the opportunity to comment on the draft preliminary risk assessment. Housenger Decl. ¶ 23-24. Penta is currently undergoing reregistration review, consistent with the procedures adopted by Congress in 1988. Thus, an administrative process has commenced and, indeed, EPA has made significant progress toward the completion of that process. See Housenger Decl. ¶¶ 14-22. Although reregistration does not prevent the Agency from using the other tools given it by Congress (such as the ability to suspend a registration), courts should be reluctant to remove a pesticide from the normal reregistration process once EPA has determined that reregistration is the most appropriate method for reassessing the risks and benefits of that pesticide.

(2) Cases cited by plaintiffs are factually distinguishable.

The D.C. Circuit was troubled in the EDF cases cited by plaintiffs that the public would be left out of the process if the Agency refused to issue a notice of intent to cancel a registration. See, e.g., Ruckelshaus, 439 F.2d at 594-595. The court did not want difficult issues "resolved behind the closed doors of the Secretary," "outside the procedures provided by statute." Id. At that time EPA had no statutorily-created reassessment process within which to review the pesticides in question, and the court saw the issuance of notices of intent to cancel as a way to

ensure the Agency's thought process was open to the public.

Unlike the situation in the EDF cases, EPA's thought process and decisionmaking on the penta registrations has been and will continue to be very open to the public. First, as evidence by plaintiffs' Complaint and Motion, EPA has already completed an in-depth review of the risks and benefits of penta as part of the Rebuttable Presumption Against Registration (RPAR) process (currently known as "Special Review"). That six-year review culminated in 1984 with the issuance of notices of intent to cancel the wood preserving uses of penta and concluded with agreements reached with registrants in 1987. 49 Fed. Reg. 28,666 (July 13, 1984); 52 Fed. Reg. 140 (Jan. 2, 1987). During the course of the penta RPAR review, EPA involved the public by taking comments on preliminary findings, holding a public meeting, and incorporating public comments, where appropriate, into the risk assessment and the benefits assessment. See Housenger Decl. ¶15.

In addition to having already completed the RPAR public reassessment of penta, EPA is currently in the middle of a second public reassessment of the penta registrations. The fact that penta was already in the reregistration process when EPA received a petition to cancel and suspend all penta registrations is a key difference between this case and the cases cited by plaintiffs because the reregistration process is being conducted in an open and transparent manner, with ample opportunities for meaningful public participation. Id. ¶¶ 24. In fact, the public nature of the process is evident from plaintiffs' own brief, which relies heavily on a draft of the science chapter of a forthcoming draft penta risk assessment that was created and made available during the reregistration process. Plaintiffs submitted comments on the draft preliminary risk assessment, and have acknowledged in those comments that they will have another opportunity to submit comments once EPA publishes the draft risk assessment. See Pl. Exh. 11, p. 1. Similarly, plaintiffs

will have the opportunity to comment on EPA's benefits assessment at a later date. Keehner Decl. ¶ 4.

Because the penta registrations are currently undergoing a public reassessment of their risks and benefits, the concerns expressed by the D.C. Circuit do not exist in the case before this Court. The procedural safeguards established in the reregistration process – both in terms of the information to be considered by the Agency and in terms of the ability of the public to participate in the reassessment – sufficiently distinguish the facts before this court from the facts in the EDF cases as to require a different result.

b. Even if plaintiffs' request for a preliminary injunction rests on a claim of unreasonable delay, they would be unlikely to succeed on the merits.

Plaintiffs' Complaint alleges, in part, that EPA has unreasonably delayed in responding to plaintiffs' petitions. Compl. ¶¶ 62-63. Although this allegation is ambiguously intertwined with allegations of "constructive denial," id. ¶ 62, Plaintiffs' Prayer for Relief seeks a "declaratory judgment that EPA has unreasonably delayed in completing its regulatory actions on the three wood preservatives . . . and in responding to Beyond Pesticides' petitions. . . ." Id. ¶ 64b. Oddly, however, plaintiffs' request for a mandatory preliminary injunction is not remotely grounded in their unreasonable delay claim. Plaintiffs provide no analysis of whether a mandatory preliminary injunction should issue on their unreasonable delay claim. Nonetheless, given that plaintiffs' Complaint is based, in part, on an unreasonable delay claim, EPA believes it is necessary to address briefly the analysis that would guide the Court should the Court address unreasonable delay in the context of this preliminary injunction.

The Court's analysis of whether to grant a mandatory preliminary injunction based on a

claim of unreasonable delay should be guided by the factors set forth by the D.C. Circuit in Telecommunications Research & Action Center v. FCC ("TRAC"), 750 F.2d 70 (D.C. Cir. 1984). In TRAC, the D.C. Circuit adopted a six-part test for determining when injunctive relief is the appropriate remedy to address agency delay. The six factors under this test are:

(1) the time agencies take to make decisions must be governed by a "rule of reason;"

(2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;

(3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake;

(4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority;

(5) the court should also take into account the nature and extent of the interests prejudiced by delay; and

(6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed."

Id. at 80 (citations and internal quotations omitted).

Plaintiffs offer no analysis of any of these factors. In this case, because EPA is moving expeditiously on its reregistration process for penta and on consideration of plaintiffs' petitions, see Housenger Decl. ¶¶ 23-25, the Court does not even need to test any agency delay against these six factors to determine if the delay is egregious enough to warrant the imposition of a mandatory preliminary injunction. TRAC 750 F.2d at 72, 80. If, however, the Court decides to test EPA's alleged delay against TRAC's six-factor analysis, these factors demonstrate that plaintiffs have no likelihood of success on the merits of their unreasonable delay claim.

With regard to the first and second TRAC factors, FIFRA provides no deadline within which EPA must grant or deny a petition for cancellation or suspension. Given the ongoing reregistration review of penta, and the status of that review, the fact that EPA has refrained from acting on plaintiffs' cancellation and suspension petition is well within the "rule of reason."

With regard to the third and fourth TRAC factors, EPA's entire docket involves matters relating to health and welfare. Thus, any benefit to health and welfare that may result from ordering EPA to issue notices of intent to cancel or suspend the penta registrations must be considered in light of competing health and welfare priorities that consume EPA's time. See Sierra Club v. Thomas, 828 F.2d 783, 798 (D.C. Cir. 1987). In balancing its competing priorities, EPA "is entitled to considerable deference in establishing a timetable for completing its proceedings," Cutler v. Hayes, 818 F.2d 879, 896 (D.C. Cir. 1987), particularly when as here the proceedings present "complex scientific and technical issues." Oil, Chem., & Atomic Workers Int'l Union v. Zegeer, 768 F.2d 1480, 1488 (D.C. Cir. 1985). Common sense dictates that a decision on plaintiffs' petitions, or completion of penta's reregistration, should not occur until EPA has completed the remaining steps in its penta reregistration process so that EPA is in a position to respond fully to public concerns and to evaluate those concerns with complete knowledge of the situation (including knowledge of the benefits of penta, which EPA has just begun to assess). Housenger Decl. ¶¶ 8-13, 23-25; Keehner Decl. ¶4. Because EPA's activities involve complex scientific and technological questions, the Agency "must be afforded the amount of time necessary to analyze such questions so that it can reach considered results in a final [decision] that will not be arbitrary and capricious or an abuse of discretion." Sierra Club, 828 F.2d at 798.

Under the fifth TRAC factor, the court is to consider the nature and extent of interests

adversely affected by the delay. In this case, the most significant fifth-factor issue is the extent to which plaintiffs may be prejudiced by any delay by EPA in acting on plaintiffs' petition. plaintiffs' alleged injuries are not caused by any delay or failure by EPA in acting on plaintiffs' petitions or completing the penta reregistration process. These injuries were allegedly occurring long before plaintiffs sent in their petitions and before they filed the instant lawsuit. Moreover, there is no certainty that plaintiffs' injuries would be remedied by the injunction they seek.[10/]

Finally, the sixth TRAC factor essentially is a negative one, pointing out that impropriety is not a necessary element of unreasonable delay. Plaintiffs have not even hinted at any agency impropriety and, thus, nothing further is required under this factor.

B. PLAINTIFFS CANNOT ESTABLISH AN IRREPARABLE INJURY

Plaintiffs are required to demonstrate that "extreme or very serious damage will result from the denial of the injunction." Columbia Hosp. For Women, 15 F. Supp. 2d at 4 (citations omitted). In assessing the potential injury to plaintiffs absent a preliminary injunction, the Court is entitled to consider plaintiffs' delay in seeking emergency relief. Where a party delays in seeking preliminary relief, the "failure to act sooner undercuts the sense of urgency that ordinarily accompanies a motion for preliminary relief and suggests that there is, in fact, no irreparable injury." Citibank, N.A. v. Citytrust, 756 F.2d 273, 276-77 (2d Cir. 1985); see also Fund for Animals v. Frizzell, 530 F.2d 982, 987-88 (D.C. Cir. 1976) (characterizing as "inexcusable" plaintiffs' in seeking injunction from time that they knew that their alleged rights had been denied; delay bolstered conclusion that

[10/]Even if EPA were to suspend penta's registration, that would not remove penta from the environment. EPA has no authority under FIFRA to, for instance, order the removal and replacement of the millions of wood telephone poles nationwide that have been treated with penta. Plaintiffs themselves contend that poles treated with penta "will stay in use for decades," and that certain constituents of penta "will remain in the environment indefinitely." Memo p. 26.

injunction should not issue). Plaintiffs assert that they have been communicating their objections to penta and related preservatives to EPA since 1997; that they petitioned EPA on several occasions over the last five years to cancel the registrations of these pesticides; that their request for cancellation is based on "findings" that EPA made in 1999; that their most recent petition was dated December 2001; and that EPA responded to this petition on February 5, 2002 declining to either grant or deny it. See Pl. Mem. App. B.

That was over ten months ago. Plaintiffs offer no explanation whatsoever for their delay in seeking judicial relief. Nor do they offer any evidence of a recent change in circumstances or some other event that was sufficiently dire to prompt them to seek a preliminary injunction during the end-of-year holiday season. Plaintiffs' claims of imminent and irreparable injury must necessarily be weighed against their own delay in seeking relief.

Plaintiffs' claim that they have been injured by EPA's alleged failure to carry out its statutory mandate must also be evaluated in light of EPA's obligation to carefully balance the risks and benefits of a pesticide. EPA does not dispute that penta (like many pesticides) potentially poses some risk of injury to individuals who come into contact with it. To support their claims of drastic and irreparable injury, however, plaintiffs rely solely on a 1999 draft preliminary risk assessment which, they contend, contains EPA's "findings" regarding the extreme risks of penta. Initially, this document is not EPA's final word on the risks of penta. Although the risk assessment portion of EPA's reregistration review of penta is nearing completion, it is still ongoing, and aspects of the risk assessment are still awaiting further internal review and/or public comment. Housenger Decl. ¶¶ 22-25. Plaintiffs recognized as much when they filed their comments on the draft preliminary risk assessment, writing "We look forward to receiving the revised science

chapter that addresses the micro-contaminants of PCP...." Plaintiffs' Exhibit 11, at 1.

Even assuming, however, that the 1999 draft risk assessment could be considered a definitive "finding" regarding the risks of penta, plaintiffs offer no unbiased evidence regarding the benefit side of the decisional equation established by FIFRA. In support of their claim that there are safer, "economically viable" alternatives to penta (and therefore that its risks outweigh its benefits), plaintiffs offer only position papers that they wrote themselves and self-serving affidavits from manufacturers of steel and fiberglass telephone poles extolling the virtues of their products.[11/] Mere allegations of the availability of efficacious alternatives do not demonstrate that consumers will actuallly turn to those alternatives; plaintiffs do not address the possibility that, instead of turning to steel or fiberglass poles, consumers will turn to poles treated with CCA or creosote. Plaintiffs' complaint asks this Court to order EPA to cancel the registrations for CCA and creosote based on risk concerns, Complaint at ¶ 64, however, granting plaintiffs' motion for preliminary injunction could have the effect of increasing the use – and therefore introduction into the environment – of these two other pesticides. Plaintiffs offer no real evidence, therefore, that risks will be reduced. At this point, it is simply impossible to tell whether or not the benefits of using penta outweigh the risks it poses. EPA has just begun its assessment of penta's benefits, and many questions remain to be answered (including questions regarding the costs and potential impact of

[11/]Plaintiffs place a great deal of emphasis on EPA's earlier decision not to cancel penta, a decision which was based in part upon the lack of viable alternatives to penta at that point. It is certainly possible that in the intervening decade, alternatives that would be viable as large-scale replacements for penta have in fact been developed (although plaintiffs' evidence is insufficient to establish this). That is why EPA needs to complete its examination of the risks and benefits of both penta and its alternatives before making any final decision.

switching to alternatives to penta – an issue which plaintiffs do not even attempt to address.)[12/] See Keehner Decl., ¶¶ 6-8.

Plaintiffs bear the burden of showing that a preliminary injunction is necessary in order to prevent "extreme or very serious damage." Veitch v. Danzig, 135 F. Supp. 2d at 35. To find that plaintiffs have shown an irreparable injury in this context, however, the Court would be required to do something that EPA itself does not yet have sufficient information to do, i.e., to evaluate the risks and the benefits of penta and conclude that the risks in fact outweigh the benefits. Before making a determination that the availability of substitutes weighs against the continued use of penta, EPA will have to examine a host of issues. See Keehner Decl. ¶ 6. Plaintiffs have simply failed to sustain their burden.

C. PLAINTIFFS CANNOT OVERCOME THE POTENTIAL IMPACT THAT THEIR REQUESTED INJUNCTION WOULD HAVE ON THE INTERESTS OF OTHER PARTIES.

Plaintiffs' claim that no harm would occur to other parties if penta were suddenly unavailable depends, again, upon their unsupported assertion that "viable substitutes exist for all of penta's uses" that would "minimize any damage from the unavailability of penta while an injunction is in force." Pl. Mem. p. 26.[13/] Plaintiffs simply assume – with no evidentiary foundation -- that

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[12/]Plaintiffs assert, with no support, that the reregistration process "does not include a re-examination of benefits." See Pl. Mem. p. 17 n.40; see also id. p. 16 (stating that EPA "does not conduct a full risk/benefit review." This is simply wrong. FIFRA incorporates considerations of "economic, social, and environmental costs and benefits into the "unreasonable risk" registration standard. 7 U.S.C. § 136(bb) (emphasis added). As discussed in the Keehner and Housenger declarations, evaluating the benefits of a pesticide is a critical component of EPA's reregistration review.

[13/]It is unsurprising that manufacturers of steel utility poles and fiberglass utility poles have submitted affidavits in support of plaintiffs' motion. However, in light of the economic interest (continued...)

such substitutes would be readily available on short notice and that they would be adequate to meet all of the needs of consumers who purchase and use penta-treated products. They also assume that current users of penta-treated poles would simply and inevitably choose to switch to the alternatives favored by plaintiffs. The alternatives cited by plaintiffs could be more expensive, more difficult to install or use, not suitable for all conditions in which penta-treated poles are used, or have other limitations. Plaintiffs have offered no evidence of the impact on consumers of penta-treated products. Moreover, plaintiffs entirely ignore the potential for disruption to EPA's ongoing review of other pesticides if EPA is forced to accelerate its consideration of penta.

D. PLAINTIFFS HAVE FAILED TO DEMONSTRATE THAT THEIR REQUESTED PRELIMINARY INJUNCTION WOULD SERVE THE PUBLIC INTEREST.

Plaintiffs' claim that there "is little or no disadvantage to the public" from making penta unavailable because there are "economically viable alternatives" is addressed above. In addition, plaintiffs make a strained argument that EPA has somehow skewed the market towards penta usage and prevented consumers from seeking alternatives to penta simply by maintaining its registration. The real market impact would come from granting the injunction that plaintiffs request – instead of a marketplace in which consumers are free to choose between penta-treated utility poles, steel poles, fiberglass poles, and whatever other alternatives there may be, the choices would be limited to non-penta-treated products.

It is simply impossible to know at this point what impacts would result from a sudden switch to non-penta-treated products. See Keehner Decl. ¶ 9. Nor is it possible to know even

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[13/](...continued)
that these affiants have in a penta-free marketplace, their testimony that their products necessarily represent viable alternatives to penta should be viewed with a critical eye.

whether those products advocated by plaintiffs would be suitable substitutes for all uses of penta-treated wood. See Keehner Decl. ¶¶ 5-6. In addition, plaintiffs have not accounted for the possibility that the public – both the wood preserving industry and consumers of treated wood – would turn to wood treated with CCA and creosote rather than to plaintiffs' preferred substitutes.

EPA still has significant work to do before it can determine whether the balance of risks and benefits suggests that the public interest would best be served by removing penta from the market. Plaintiffs thus are asking the Court to make a determination that EPA itself is not yet ready or able to make responsibly. Plaintiffs' one-sided and self-serving evidence falls far short of establishing that the public interest would be served by immediately removing penta from the market.

IV. CONCLUSION

For the foregoing reasons, plaintiffs' Motion for Preliminary Injunction should be denied.

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