IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

BEYOND PESTICIDES/ NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES, et al.,

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v. Civil Action No. _____

CHRISTINE T. WHITMAN, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY, et al.,

Defendants.

PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION

INTRODUCTION

Plaintiffs Beyond Pesticides/National Coalition Against the Misuse of Pesticides ("Beyond Pesticides"), Communications Workers of American ("CWA"), Center for Environmental Health ("CEH"), and Joseph S. Prager and Rosanne M. Prager seek a preliminary injunction compelling defendant Christine T. Whitman, Administrator of the Environmental Protection Agency ("EPA") and EPA to issue a notice of cancellation of the registrations of all products containing pentachlorophenol ("penta") intended for use as wood preservatives, pursuant to 7 U.S.C. § 136d(b)(1), and at the same time to issue an emergency order pursuant to 7 U.S.C. § 136d(c)(3) to suspend immediately those registrations. ¹ EPA issued preliminary findings in 1999 concerning the health hazards of the wood preservative use of penta to children and to utility and wood treatment workers which vastly exceed EPA's own action thresholds and meet the standards for emergency action under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. Specifically, EPA found cancer risks to children up to 220 times higher than its usual action trigger for unreasonable risk. For one category of workers, EPA found a more than 100% lifetime risk of cancer (i.e., multiple cancers per worker), and risks to other categories of workers ranging from ten to a thousand times the "acceptable" threshold that EPA applies to occupational exposures. Despite these alarmingly high preliminary risk findings, and

¹ The complaint filed in this matter seeks the cancellation and suspension of registrations and other relief based upon EPA's inaction and unreasonable delay with regard to three wood preservatives which EPA has considered together in its regulatory reviews; penta, creosote and chromated copper arsenate ("CCA"). The preliminary injunctive relief sought by this motion is limited to the cancellation and emergency suspension of penta, due to EPA's 1999 findings of extremely high risk to the public from this pesticide. Plaintiffs also plan to file a motion for summary judgment seeking a determination based on the undisputed facts before the Court that plaintiffs are entitled to all of the relief sought in the complaint.

plaintiff Beyond Pesticides' repeated petitions for action, EPA has failed and effectively refused to finalize these findings or to take appropriate protective action.

Moreover, as long ago as 1984, after a six year exhaustive analysis, EPA determined that the risks associated with the wood preservative uses of penta would warrant cancellation of penta's registration, but for the lack of economically viable alternatives. Since the 1984 decision, economically viable alternatives for all of penta's wood preservative uses have been developed and made commercially available. Information concerning alternative products has been brought to EPA's attention repeatedly, beginning at least as early as 1993. The availability of these cost-effective alternatives has removed EPA's sole justification for penta's continued registration.

Because of the extremely high risks of injury and death posed by continued use of penta, preliminary relief is warranted until this case can be heard on the merits. If the Court orders EPA to suspend penta's registration on an emergency basis, sale and use of penta and the attendant risks to the public will be halted immediately. However, the ultimate decision concerning the future use of penta will be subject to this Court's consideration on the merits, and as well to elaborate procedural protections under FIFRA, which provides for adjudicatory suspension and cancellation hearings where all of the relevant scientific and economic issues are explored in great depth. 7 U.S.C. § 136d(b), (c)(2) and (d). The Court's order would merely provide the interim protection from an "imminent hazard" which EPA is required to, but has failed to provide under FIFRA. 7 U.S.C. § 136d(c).

Plaintiffs do not ask the Court to make any determinations of contested scientific or economic issues, or to second guess EPA's findings in these areas. Rather, plaintiffs ask the Court to determine that findings EPA *has already made* meet the statutory standards for cancellation and emergency suspension.

STATEMENT OF FACTS

- 1. Pentachlorophenol ("penta") is an aromatic chlorinated hydrocarbon chemical derived from coal and oil. At one time it was used in agricultural pesticides, antimicrobials, mossicides, disinfectants and defoliants. However, those uses were banned by EPA in the 1980's and 1990's because they posed excessive human health and environmental risks, including cancer and birth defects. Today, penta's primary use is as a wood preservative to protect utility poles from fungus, insects and decay.²
- 2. As of 1995, approximately 656 million pounds of penta were used annually.³ Based on utility and industry data, plaintiff Beyond Pesticides estimated in 1997 that there were over 116 million wood preservative-treated utility poles in the United States, approximately 45% of them (over 52 million) treated with penta, and the remainder with CCA and creosote.⁴ These utility poles are ubiquitous: along roadways and in residential and school yards, parks and playgrounds. Because of penta's persistent nature, utility poles treated with penta have a useful life of 30 to 50

² Penta is also currently registered for use for wood protection treatments to existing buildings, wooden containers for growing plants, aquatic structures, and finished wood products. Examples of penta-treated products include lumber, fencing, porches, posts, shingles, groundline building components, steps, walkways, laminated beams, pilings, piers, docks, bridges and trusses. U.S. Environmental Protection Agency, 1999, Science Chapter for the Reregistration Eligibility Decision Document (RED) for Pentachlorophenol (PC Code: 063001, Registration Case Number 2505), (hereinafter "EPA Penta Science Chapter"), at 15, Exhibit 3. The treatment of utility poles accounts for the great bulk of the remaining use of penta.

³ American Wood Preservers Institute, 1996. "The 1995 Wood Preserving Industry Protection Statistical Report," at 12, Exhibit 4. The Statistical Report shows 39,734,000 gallons of oilborne preservatives. This converts to 655,611,000 pounds using a density conversion of 8.97 pounds per gallon.

⁴ National Coalition Against the Misuse of Pesticides, 1997, "Poison Poles – A Report About their Toxic Trail and Safer Alternatives," (hereinafter "Poison Poles") at 13, 19, Exhibit 5. Based on 1992 data, EPA estimated that there were 60 million utility poles in service in the United States, 36 million of them treated with penta. EPA Penta Science Chapter at 24-25, Exhibit 3.

years,⁵ and some of penta's constituents, which are considered persistent organic pollutants, remain in the environment indefinitely. *See*, \P 4, *infra*.

- 3. The process of treating wood with preservatives creates enormous environmental and public health hazards. Wood treatment plants often become Superfund hazardous waste sites due to contamination of the surrounding environment by wood preservative chemicals.⁶ Penta has been found in at least 314 of the sites on EPA's National Priority List of Superfund clean-up sites.⁷
- 4. Because of concerns about its health and environmental hazards, penta has been totally banned or severely restricted in many countries throughout the world.⁸ Penta and its contaminants are classified as "persistent organic pollutants" by the United Nations Environment

⁵ 1995 Wood Preserving Industry Production Statistical Report at 1, Exhibit 4.

⁶ The "Superfund" program for clean-up of hazardous waste sites was created by the Comprehensive Environmental Response, Compensation and Liability Act, 52 U.S.C. § 9601 *et seq.*

⁷ "Poison Poles," at 14 and n. 27, Exhibit 5.

Beyond Pesticides, National Coalition Against the Misuse of Pesticides, December, 1999. "Pole Pollution – New Utility Pole Chemical Risks Identified by EPA While Survey Shows Widespread Contamination," (hereinafter "Pole Pollution"), at 4, Table 1 and n. 12, Exhibit 7. *See*, United Nations Environmental Programme, "Prior Informed Consent Decision Guidance Document," available at www.chem.unep.ch, at http://193.247.37.2/picsite/chemicals-to-del/5%20-third%20set%20of%20pesticides/pentachlorophenol/penta.doc; United Nations, "Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments," Fifth Issue, 1994, Exhibit 6; European Union Commission Decision, Oct. 26, 1999 (1999/831/EC) at 1.(5), available from http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/l_329/-l-32919991222en00150024.pdf (Any substance to which penta has been added intentionally may not be sold or used in any European Union country as of Sept. 2000, except that 5 countries may continue under less than total restriction until Dec. 31, 2008).

Programme ("UNEP").⁹ Some of penta's carcinogenic contaminants, hexachlorobenzene ("HCB"), dioxins, and polychlorinated dibenzofurans ("furans"), are restricted by the Stockholm Convention on Persistent Organic Pollutants, signed by the United States in 2001.¹⁰

- 5. Beginning in 1978, because of concerns including cancer, genetic mutations and birth defects, EPA began a regulatory review, called the "Rebuttable Presumption Against Registration" ("RPAR"), of penta, creosote and CCA. In 1984, EPA made a decision to retain the wood preservative uses of penta, with certain risk-mitigating measures, despite findings of elevated risks of cancer, birth defects and fetotoxicity (toxicity to fetuses), because of the asserted high economic benefits from its use and the lack of economically viable alternatives. EPA has not reevaluated the availability of safer alternatives since that time.¹¹
- 6. Over the next several years, EPA cancelled the pesticide registrations for all uses of penta, CCA and creosote, except wood preservative use. In 1987, when EPA cancelled most non-wood use penta products, including herbicides, antimicrobials, disinfectants, mossicides and defoliants, it stated.

The Agency is concerned about the ubiquity of pentachlorophenol, its persistence in the environment, its fetotoxic and teratogenic [birth defect-inducing] properties,

⁹ United Nations Environment Programe, November, 1999. "Inventory of Information Sources on Chemicals: Persistent Organic Pollutants" at 1 (penta contaminants), 15, 17 (penta). Available at http://www.chem.unep.ch/pops/pdf/invsrce/inventpopscomb.pdf

¹⁰ See, Bush, G.W., C. Powell, C. Whitman. 2001. Remarks by the President, Secretary of State Colin Powell and EPA Administrator Christine Todd Whitman in Environmental Announcement. Office of the Press Secretary, April 19, 2001, available at http://www.whitehouse.gov/news/releases/2001/04/20010419-2.html; UNEP Press Release, "Governments Finalize Persistent Organic Pollutants Treaty," December 10, 2000, available at http://www.chem.unep.ch/pops/princ5.htm.

Appendix A.

its presence in human tissues and its oncogenic [cancer-causing] risks from the presence of dioxins in the technical material.

52 Fed. Reg. 2282, 2283 (Jan. 21, 1987). EPA rejected the option of adopting risk reducing measures similar to those adopted for the wood preservative uses, noting that the wood preservative registrations were maintained with modifications because "those uses entailed very high benefits. Here, with similar risk concerns, the risk/benefit balance weighs heavily on the side of risk because of the low benefits." *Id.* at 2288.

7. Since 1997, EPA has been reassessing penta as part of the reregistration of older pesticides required by FIFRA, 7 U.S.C. § 136a-1(a). In 1999, EPA's Risk Assessment and Science Support Branch (RASSB)/ Antimicrobial Division produced a preliminary Science Chapter on penta for a Reregistration Eligibility Decision document ("RED"). EPA Penta Science Chapter, Exhibit 3. In that report, EPA made the following findings, based on the risk of penta alone, without consideration of its persistent carcinogenic contaminants:¹²

— The lifetime cancer risk to children exposed to soil contaminated with penta leaching from utility poles was as high as 2.2 in10,000 (2.2 x 10-4), and contact with the treated wood itself posed a cancer risk of 6.4 in one million (6.4 x 10-6). These risks are, respectively, 220 and 6.4 times EPA's usual one-in-a-million threshold for "acceptable" risk. 14

¹² In the memorandum accompanying the EPA Penta Science Chapter, Exhibit 3, first page, EPA stated that the report addressed only penta as the active ingredient, and not its dioxin and furan microcontaminants. EPA stated that "a separate document on the microcontaminants will be forthcoming." However, no such document has yet been produced.

¹³ EPA Penta Science Chapter at 125, Table 10, Exhibit 3.

When Congress amended FIFRA in 1996 in the Food Quality Protection Act, the Commerce Committee report stated: "It is the Committee's understanding that, under current EPA practice . . . EPA interprets a negligible risk to be a one-in-a-million lifetime risk. The Committee expects the Administrator to continue to follow this interpretation." House Report No. 104-669(II) (Committee on Commerce) (July 23, 1996) at 41, *reprinted in*, 1996 U.S. Code Cong. and Admin. News 1280.

- Residues of penta in drinking water, along with exposure from food and residential uses, "pose an unacceptable chronic risk to children." EPA Penta Science Chapter at 7.
- With regard to occupational exposures, despite risk reduction measures EPA had adopted in the 1980's, EPA found, based on "maximum protective measures," that 13 out of 14 exposure scenarios had unacceptable cancer risks. ¹⁵ Certain categories of workers had lifetime cancer risks as high as 1.8 and 4.4 in 10, and 6.2 and 8.4 in 100, ¹⁶ up to more than 4,400 times EPA's "acceptable" level of risk for occupational exposures, and 440,000 times the usual one per million standard. ¹⁷ Utility pole installers were found to have a cancer risk of 6.6 in 1000, sixty-six times the "acceptable" occupational level or 6,600 times the general level. ¹⁸ Most extreme, applicators of grease formulations of penta as groundline retreatments for existing utility poles had a risk of 3.4 out of 1 (apparently because an exposed worker who survived and continued in this occupation could be expected to incur additional cancers), 3.4 million times the "acceptable level" for the general population (34,000 times the occupational level). ¹⁹
- —Chronic non-cancer risks for occupational handlers "exceed the Agency's level of concern using maximum protective measures . . . for all scenarios." *Id.*, at 1.
- EPA reaffirmed its earlier findings on the teratogenic and fetotoxic properties of penta. *Id.*, at 59-60.
- 8. In the 18 years since EPA concluded the wood preservatives RPAR review with a determination that despite risks which would otherwise mandate cancellation, continued use was justified by the lack of economically viable alternatives, a number of adequate substitutes for penta-treated wood have become available, and the capacity for production of previously-known

¹⁵ *Id.* at 2.

¹⁶ *Id.* at 108, Table 6.

¹⁷ EPA's "risk level of concern" for occupational exposures is 1 in 10,000 (1 x10-4). *Id.* at 2. EPA does not explain why it applied a hundred-fold less protective standard to occupational exposures than the congressionally-approved one in a million "negligible risk" it applies to the public at large.

¹⁸ *Id.* at 120, Table 8.

¹⁹ *Id.* at 108, Table 6.

substitutes has increased to the point where the perceived "immense" "economic impact" that EPA relied upon as the basis for its decision to retain the registrations has diminished to the point of vanishing.²⁰

- 9. Manufacturers of alternatives to treated wood utility poles have made submissions to EPA and have had meetings with EPA officials concerning the environmental, economic, and performance advantages of their products as compared with treated wood. For example, producers of steel utility poles have been in communication with and had meetings with EPA beginning in 1993.²¹ In 2001, Mr. Joseph Reilly, president of a company which produces a fiberglass alternative to treated wood utility poles, made a presentation concerning his product to staff at EPA's Office of Pesticide Programs' Biological and Economic Analysis Division. His presentation demonstrated that fiberglass poles are being used by utilities in place of treated wood poles, and are non-toxic and economically competitive with treated wood.²²
- 10. Beyond Pesticides has communicated information about economical alternatives to pesticide-treated wood to EPA a number of times in various forms over the years since the conclusion of the 1984 regulatory RPAR review. Most notably, in 1997 Beyond Pesticides submitted to EPA its report entitled, "Poison Poles: A Report About Their Toxic Trail and Safer Alternatives." Exhibit 5. The report contains a detailed analysis, including cost comparisons, of the available substitutes for treated wood utility poles, such as recycled steel, concrete, fiberglass reinforced composite and the burial of utility lines. The report concludes by urging that

²⁰ See Appendix A, ¶ 2, p. A-2.

²¹ Affidavit of Robert G. J. Jack, Ex. 1, ¶ 9.

²² Affidavit of Joseph W. Reilly, Ex. 2, ¶ 9.

"hazardous wood preservatives . . . be removed from the market." (p. 38).

- 11. Between 1997 and 2001, Beyond Pesticides and others submitted a series of letters, reports, comments and petitions to EPA seeking the cancellation and suspension of penta's registration, including up-to-date information about the hazards of penta and about alternatives to penta-treated wood.²³ These included Beyond Pesticides' 1997 "Poison Poles" report, Exhibit 5, and the 1999 "Pole Pollution" report, Exhibit 7. The 1999 report reviewed the EPA Penta Science Chapter, noting EPA's findings of extremely high risks to utility workers and children, as well as factors not considered by EPA which would lead to even higher risk findings. For example, it reported a survey of utility companies which revealed that over 68% of the respondent utilities gave or sold their discarded poles to be reused by the public, resulting in exposures not considered by EPA. "Pole Pollution" at 11-12, Exhibit 7. Based on responses to the survey concerning the cost to utilities of various types of poles, the report concluded that "the cost differential between treated wood and recycled steel poles is negligible in the short-term and benefits steel in the long-term." *Id.* at 7.
- 12. EPA's various responses to these letters, reports and petitions repeated that the Agency was currently reviewing penta as part of its process for the reregistration of older pesticides, which review it originally stated would be completed in FY 1998. *See*, Appendix B, ¶¶ 2, 7 and 12; Exhibits 10, 13, and 15. EPA's most recent response, on March 5, 2002, again stated that the wood preservative pesticides were undergoing reregistration review and that the agency was "proceeding as rapidly as feasible to resolve your concerns." It offered no timetable

²³ A detailed chronology of the petitions for cancellation and suspension and other submissions to EPA and EPA's responses is included in Appendix B. The relevant documents are attached as exhibits 5, 7, and 9 through 17 hereto.

for completion of review. Appendix B, ¶ 12, Exhibit 17.

LEGAL FRAMEWORK

1. The Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA")

The primary purpose of FIFRA, 7 U.S.C. § 136, et seq., is to "regulate the use of pesticides to protect man and his environment." FIFRA requires all pesticides which are distributed or sold in the United States to be registered with the Administrator of EPA. 7 U.S.C. § 136a(a). The Administrator is to approve the registration of a pesticide only if he finds, inter alia, that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). "Unreasonable adverse effects on the environment" is defined, in relevant part, to mean "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). Thus, in determining whether or not to register a pesticide or to cancel its registration, EPA engages in a cost/benefit analysis.

2. Cancellation, Suspension and Emergency Suspension of Pesticide Registrations

Whenever it appears that a pesticide does not meet the statutory standard, EPA must issue a notice of cancellation of the pesticide's registration. 7 U.S.C. § 136d(b); Environmental

Defense Fund ("EDF") v. EPA, 465 F.2d 528, 533 (D.C. Cir. 1972); Love v. Thomas, 858 F.2d

1347, 1350 (9th Cir. 1988), *cert. denied sub nom* AFL-CIO v. Love, 490 U.S. 1035 (1989).

Interested parties may request formal adjudicatory hearings, during which sale and use of the

²⁴ S. Rep. 92-838 (Committee on Agriculture and Forestry), June 7, 1972, *reprinted in*, 1972 U.S. Code Cong. & Admin. News at 3993.

pesticide is permitted to continue. 7 U.S.C. § 136d(b) and (d). EPA cancellation hearings have generally taken a year to two years or more.²⁵

Because of this "elaborate procedural protection against improvident cancellations," <u>EDF v. EPA</u>, 465 F.2d at 533, FIFRA also provides two levels of suspension. An ordinary suspension may be ordered "[i]f the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation. . . .". 7 U.S.C. § 136d(c)(1). The registrant may request an expedited hearing on the question of whether an imminent hazard exists, and use may continue during that hearing. 7 U.S.C. § 136d(c)(1) and (2). "Imminent hazard" is defined to mean "a situation which exists when the continued use of a pesticide during the time required for cancellation proceedings would be likely to result in unreasonable adverse effects on the environment ...". 7 U.S.C. § 136(l). Suspension hearings generally consume a few months. ²⁶
The alternative to an ordinary suspension preceded by a hearing is an emergency suspension: "Whenever the Administrator determines that an emergency exists that does not permit the Administrator to hold a hearing before suspending," an emergency order may be issued which becomes effective immediately. The registrant may request a suspension hearing, but the suspension remains in effect during the hearing. 7 U.S.C. § 136d(c)(3).

Unlike statutory schemes where the burden is on the agency to justify its proposed regulatory actions, under FIFRA, "Congress ... deliberately shifted the ordinary burden of proof under the Administrative Procedure Act, requiring manufacturers to establish the continued safety

²⁵ See, S. Rep. 92-970 (Committee on Commerce), July 19, 1972, reprinted in, 1972 U.S. Code Cong. & Admin. News at 4094; <u>Love v. Thomas</u>, 858 F.2d at 1350 and n.2.

²⁶ E.g., <u>Love v. Thomas</u>, 858 F.2d at 1363 (Administrator estimated it would take four months to complete a suspension hearing).

of their products." <u>Industrial Union v. American Petroleum Institute</u>, 448 U.S. 607, 653, n.61 (1980).²⁷

3. Judicial Review of EPA's Failure to Cancel or Suspend Pesticides

FIFRA provides for U.S. District Court review of "the refusal of the Administrator to cancel or suspend a registration not following a hearing...". 7 U.S.C. § 136n (a). The case law makes clear that EPA's failure to cancel or suspend a pesticide may be challenged in court even when EPA asserts that it still has the matter under consideration. EDF v. Ruckelshaus, 439 F.2d 584, 592-93 (D.C. Cir. 1971). Even short-term inaction is considered tantamount to denial of a request to suspend a pesticide's registration, since suspension is designed to protect from an "imminent hazard." EDF v. Hardin, 428 F.2d 1093, 1099 (D.C. Cir. 1970); accord, EDF v. EPA, 465 F.2d at 533 (a refusal to suspend is a final order reviewable immediately because of the potential for delay and the consequent possibility of serious and irreparable environmental damage).

4. The Rebuttable Presumption Against Registration and Special Review

The expectation of Congress when it enacted FIFRA, as interpreted by the courts, was that cancellation notices would issue after "a reasonable preliminary investigation," as soon as a "substantial question of safety" arose. The full exploration of the issues would occur at the

²⁷ See also, e.g., "Creosote, Pentachlorophenol and Inorganic Arsenicals; Intent to Cancel Registrations," 49 Fed. Reg. 28666, 28667 (July. 13, 1984): "The burden of proving that a pesticide satisfies the registration standard is on the proponents of registration and continues as long as the pesticide is registered. Under section 6 of FIFRA, the Administrator may cancel the registration of a pesticide or require modification of the terms and conditions of registration whenever it is determined that the pesticide causes unreasonable adverse effects on the environment."

cancellation hearing. EDF v. Ruckelshaus, 439 F.2d at 595. 28

Instead, by regulation EPA has established elaborate procedures to analyze the risks and benefits of pesticides which appear to pose unreasonable risks prior to the issuance of a cancellation notice. In 1975, EPA instituted its "Rebuttable Presumption Against Registration" ("RPAR") process, to which the wood preservative pesticides were subject. Former 40 C.F.R. § 162.11. The RPAR regulations set forth certain risk criteria related to acute toxicity, hazards to wildlife, chronic toxicity (including cancer), and the lack of emergency treatments. If a pesticide met or exceeded these criteria, an RPAR would be initiated, and if the risk presumptions were not rebutted, EPA was required to initiate cancellation proceedings. Former 40 C.F.R. §162.11(a)(1) – (5).²⁹ RPAR's typically consumed two to six years before final regulatory resolution.³⁰ In the case of penta and the other wood preservatives, it was six years until a final regulatory decision, which was then challenged by registrants requesting the statutory cancellation hearings, and ultimately resolved by negotiated settlements two and three years later. *See*, Appendix A, ¶¶ 1-3, 5 and 6.

The RPAR procedures applied to the wood preservatives consisted of three stages. First,

²⁸ See also, National Coalition Against the Misuse of Pesticides ("NCAMP") v. EPA, 867 F. 2d 636, 643-44 (D.C. Cir. 1989)("substantial question of safety" standard for cancellation "is perhaps even less rigorous than the typical 'reason to believe' with which many agencies begin enforcement proceedings. ... Analytically, a notice of intent to cancel is little more than 'a determination . . . that adjudicatory proceedings will commence."")(citations omitted).

²⁹ See also, "Creosote, Pentachlorophenol and Inorganic Arsenicals; Intent to Cancel Registrations," 49 Fed. Reg. at 28667 ("Unless all presumptions of risk are rebutted, the RPAR is concluded by issuance of a Notice of Intent to Cancel.").

³⁰ Proposed Rule, "Special Review of Pesticides Criteria and Procedures," 50 Fed. Reg. 12188, 12189 (March 27, 1985).

there was an initial investigation involving a review of scientific studies, validation of those studies by EPA scientists or contractors, and an extensive literature search to identify health and environmental effects information. A preliminary assessment of exposure to the pesticide was made. The pesticide registrants were informed of the review and offered the opportunity to submit comments and information. At the conclusion of this phase, the RPAR notice was published in the Federal Register³¹ and EPA's Position Document 1 ("PD 1") was made available to the public. 50 Fed Reg. at 12191.

In the second phase, EPA gathered additional information in the form of rebuttal comments, additional information on risk, and input from other agencies. Because, in the case of the wood preservatives, the rebuttal was not successful, EPA prepared and issued a Position Document 2/3 (PD 2/3), including a rebuttal assessment, risk assessment, benefits assessment, risk/benefit analysis and proposed regulatory position.³² A notice of EPA's position and the availability of the PD2/3 was published in the Federal Register.³³

In the third phase, as required by FIFRA for proposed cancellation decisions, 7 U.S.C. 136w(d) and 136d(b), the decision was submitted to the Scientific Advisory Panel and the Secretary of Agriculture for comment. EPA also solicited comments from the industry and the public. Then EPA reviewed all of these comments and then published its final regulatory decision

³¹ See Appendix A, p. A-1, n.1.

³² 50 Fed. Reg. at 12191.

³³ See Appendix A, ¶ 2.

in the Federal Register,³⁴ supported by the risk/benefit evaluation in the Position Document 4 (PD 4).³⁵ Because EPA's final decision on the wood preservatives was a Notice of Intent to Cancel unless proposed risk mitigation measures were adopted, interested parties then had the opportunity to request the adjudicatory cancellation hearings provided in the statute. Hearings were requested on the 1984 mitigation measures, resulting in a settlement and the publication of modified measures in 1986. Then the restrictions on dioxin contaminants in penta were challenged in 1986, resulting in a settlement which weakened those restrictions in 1987. *See*, Appendix A, ¶¶ 5 and 6.

In 1985, EPA revised its regulations and renamed the RPAR procedure "Special Review." 50 Fed. Reg. 49003 (Nov. 27, 1985). The Special Review procedures, found at 40 C.F.R 154.1 *et seq.*, are similar to the RPAR procedures, with some modifications.³⁶ In the case of the wood preservatives, the review was begun under the RPAR regulations, but finally completed under the Special Review regulations in 1987. The changes in the regulations had no effects relevant to the wood preservatives proceedings.³⁷

³⁴ See Appendix A, \P 3.

³⁵ 50 Fed. Reg. 12191.

The Special Review Process is described in the Federal Register Notice adopting the regulations, 50 Fed. Reg. 49003, and in EPA's 1998 report, "Status of Pesticides in Registration, Reregistration and Special Review (Rainbow Report)," at 11-13, available at www.epa.gov.oppsrrd1/Rainbow/98rainbo.pdf.

See, "Creosote, Pentachlorophenol, and Inorganic Arsenicals; Amendment of Notice of Intent to Cancel Registrations," 51 Fed. Reg. 1334, 1335 (January 10, 1986) (discussing initiation of the proceeding under the RPAR criteria and reaffirming the decision based on the RPAR process, and referring to "Special Review" as "(previously referred to as the Rebuttable Presumption Against Registration ("RPAR"))" See also, "Conclusion of Special Review,

EPA recognizes that utilization of these interim review procedures is not required by statute and that "[i]n lieu of Special Review, the Agency may elect to issue an immediate notice of intent to suspend, cancel, or deny registration ...". 50 Fed. Reg. 49003, 49007.

5. Reregistration

FIFRA requires the reregistration of all pesticides first registered before November 1, 1984. 7 U.S.C. § 136a-1(a). The purpose of reregistration is to ensure "that older pesticides meet contemporary health and safety standards and product labeling requirements, and that their risks are mitigated." The reregistration process involves the submission of additional studies and data by the registrants. EPA then reviews the submitted materials and issues a "Reregistration Eligibility Decision" ("RED") which determines "whether the data base is substantially complete and whether or not the pesticide causes unreasonable adverse effects to people or the environment when used according to product labeling." *Id.*, at 62.

Despite the fact that a reregistration decision is intended to determine whether or not the pesticide meets the statutory standard for registration, EPA generally does not conduct a full risk/benefit review in this context, but rather focuses on updating studies and information concerning the potential risks posed by the pesticide. When it proposed the current Special Review procedures, even though the statutory standards applied in registration, reregistration and

Inorganic Arsenicals" [Non-wood], 58 Fed. Reg. 64579, 64580 (Dec. 8, 1993) ("EPA issued a Notice of Rebuttable Presumption Against Registration (hereafter referred to as Special Review) for the wood preservative and non-wood preservative uses of inorganic arsenicals Based on ... the risk criteria for carcinogenicity, teratogenicity and mutagenicity under 40 CFR 162.11 (these criteria are now found at 40 CFR 154.7)."

³⁸ "Rainbow Report, at 61.

Special Review proceedings are the same, EPA distinguished the "in-depth review of the risks and benefits posed by a pesticide" in Special Review from "the routine reviews that the Agency conducts in making most registration and reregistration determinations. . ."³⁹. In particular, EPA does not generally conduct a benefits review, in order to determine whether the risks posed by a pesticide are justified by its benefits, in its reregistration reviews.⁴⁰

In response to a 1997 letter concerning the wood preservatives from twelve scientists and public health officials, EPA replied "A RED on penta is expected in FY 1998 You have suggested that EPA address . . . alternative materials After the Agency completes the penta RED, it may make sense to carry out such a reassessment." (Emphasis supplied). Exhibit 10; see, Appendix B, ¶ 2. Thus, despite two decades of accumulated and unrefuted findings of elevated risk, the Agency has chosen to address the hazards of penta through its routine re-registration process rather than through a Special Review or through the statutory scheme of a cancellation and suspension proceeding. Furthermore, it has stated explicitly that its current (and by its own admission four years overdue) re-registration review will not include an analysis of alternatives, the lack of which was the sole justification for its prior determination to retain penta's registration.

³⁹ 50 Fed. Reg. at 12192.

⁴⁰ In a report entitled "EPA's Use of Benefit Assessments in Regulating Pesticides," GAO/RCED-91-52 (March 1991), the General Accounting Office ("GAO") stated that EPA generally waives submission of benefits data in the registration process. "Typically, EPA formally examines benefits primarily during its special review process, designed to assess risks and benefits of registered pesticides suspected of posing unreasonable adverse effects." Report at 9. GAO concluded that "[t]he main role of benefit analysis in EPA's pesticide regulatory scheme is to provide input for special review." *Id.*, at 14. Available at www.gao.gov.

ARGUMENT

The requirements for preliminary injunctive relief in this Circuit are:1) a substantial likelihood of success on the merits; 2) irreparable injury absent an injunction; 3) no substantial injury to other interested parties from the injunction; and 4) that the public interest would be furthered by the injunction. City Fed Financial Corp. v. Office of Thrift Supervision, 58 F.3d 738, 746 (D.C. Cir. 1995). The court is to "balance the strengths of the requesting party's arguments in each of the four required areas. If the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak." *Id.*, 58 F.3d at 746. *Accord*, Davenport v. International Brotherhood of Teamsters, 166 F.3d 356, 360-61 (D.C. Cir. 1999). An injunction may issue "with either a high probability of success and some injury, or vice versa." Miami Bldg. & Const. Trades Council v. Secretary of Defense, 143 F. Supp.2d 19, 24 (D.D.C. 2001), quoting Cuomo v. Nuclear Regulatory Commission, 772 F.2d 972, 974 (D.C. Cir. 1985).

In this case, all four factors strongly favor the grant of a preliminary injunction.

1. Plaintiffs Have a Strong Likelihood of Success on the Merits

Plaintiffs have a strong likelihood of success on the merits because EPA itself has found that the hazards posed by penta would warrant cancellation if there were economically viable alternatives, and EPA no longer has a reasonable basis for its 18-year-old finding that there are no such alternatives. Moreover, EPA has recently found even more extreme risks to the public which cannot be balanced against any compelling need for continued use, thus warranting emergency action

EPA is required to take appropriate action to cancel and suspend pesticide registrations when the statutory standards for those actions are met. EDF v. Ruckelshaus, 439 F.2d at 593 (decision not to cancel reviewable based on the claim that the agency already has findings requiring cancellation). EPA must issue a cancellation notice whenever there is a substantial question about the safety of a registered pesticide. Love v. Thomas, 858 F.2d at 1350 (citations omitted). With regard to suspension, once EPA has determined that cancellation is warranted, (as EPA did regarding the wood preservatives but for the lack of viable alternatives), "[i]f there is no offsetting claim of any benefit to the public, then the EPA has the burden of showing that the substantial question of safety does not pose an 'imminent hazard' to the public." EDF v. EPA, 465 F.2d at 539.⁴¹

Eighteen years ago, after 6 years of exhaustive review and attempted rebuttal by the advocates of continued use, EPA made findings that the wood preservative uses of penta posed risks of birth defects, cancer, and fetotoxicity which would have warranted cancellation but for the lack of economically viable alternatives. All other uses of penta, for which there were economically viable alternatives, have been canceled by EPA. When EPA decided to cancel most of penta's non-wood uses in 1987, the Agency specifically stated that the wood preservative uses of penta posed "similar risk concerns" but that those registrations were maintained because

The D.C. Circuit reaffirmed this standard in <u>NCAMP v. EPA</u>, 867 F. 2d at 644, while emphasizing that the standards for cancellation, suspension and emergency suspension were not to be conflated, but vary along a continuum as to the immediacy of the harm and the quality and quantity of the evidence.

⁴² *See*, Appendix A, ¶¶ 1-4.

⁴³ See, Statement of Facts, p.5-6, ¶ 6, supra; App. A at ¶ 7 and n.5.

of "very high benefits;" *i.e.*, were it not for the "very high benefits," the wood preservative uses of penta would also be canceled. Since that time, no subsequent review of penta's risks has reduced the risk concerns that supported those conclusions; to the contrary, risk concerns have only increased. And, over the course of several years, EPA has been presented with evidence of safer available and currently-utilized, economically-viable alternatives to penta as a wood preservative. As a result, the "very high benefits" which upon which EPA's decision to allow continued use of penta was based no longer exist, and the "similar risk concerns" to the non-wood uses of penta now merit cancellation of wood preservative uses also. Yet, EPA has failed to take the statutorily required action to cancel penta's registration at any time that the pesticide causes "unreasonable adverse effects on the environment,", *i.e.*, its risks exceed its benefits.

EPA's current review of penta in the reregistration process has already consumed five years, with no end in sight. Moreover, as currently implemented by EPA, the reregistration process is not even the appropriate vehicle to determine whether use of penta should continue, since it does not include a re-examination of benefits, which alone would lead to action to cancel penta's registration. Thus, the reregistration review has actually delayed cancellation action which should have taken place at least nine years ago when EPA was informed of viable

⁴⁴ See, Statement of Facts, p. 6-7, ¶ 7, supra; Appendix A, ¶ 8.

⁴⁵ *See*, Statement of Facts, pp. 7-9, ¶¶ 8-10, *supra*; Affidavits of Robert G. J. Jack and Joseph W. Reilly, Exhibits 1 and 2. Where EPA has been presented with information that alternative pest control mechanisms are available, a decision not to suspend must address whether those alternatives are available or feasible. EDF v. EPA, 465 F.2d at 539.

alternatives.⁴⁶ EPA's updated risk analysis in the reregistration review, as reflected in the 1999 Penta Science Chapter, however, has added greatly to risk concerns, which, if there was any doubt before, now unquestionably rise to the level of an "imminent hazard" and an "emergency" under FIFRA, requiring an emergency suspension.

EPA found an alarmingly high lifetime risk of cancer to workers re-applying penta to utility poles. (EPA's finding suggests that in a typical cohort of such workers the number of cancers induced by lifetime occupational exposure to penta would be more than three times the number of workers). EPA also found lifetime cancer risks of up to 2 in 10 to other categories of workers, two thousand times EPA's threshold for "unreasonable risk" for occupational exposures and 200,000 times the "acceptable" risk level EPA applies to the general public.⁴⁷ These risks are much higher than those found in 1984 in the RPAR, even with maximum mitigation measures, completely belying any expectation EPA might have had in1984 that mitigation measures could reduce risks to acceptable levels.⁴⁸ Adding further to the urgency of the situation, EPA found not

⁴⁶ If EPA had initiated cancellation action when it learned of alternatives in 1993, instead of beginning a lengthy reregistration process, even if cancellation hearings had been requested and no suspension action had been taken, certainly penta would have been off the market by now. Thus, even an emergency suspension now would result in a later removal from the market than would have taken place had EPA acted on the information about alternatives.

⁴⁷ See Statement of Facts, p.6-7, ¶ 7, supra. When it determined to cancel the use of inorganic arsenicals (which are a component of the wood preservative CCA) on cotton, EPA stated that cancer risks to workers higher than one in one hundred "are considered unreasonable within the meaning of FIFRA section 2(bb)," despite the existence of "moderate benefits" and the fact that "alternatives are not as efficacious." "Inorganic Arsenicals, Preliminary Determination to Cancel," 56 Fed. Reg. 50576, 50584 (Oct. 7, 1991).

⁴⁸ Of course, since EPA in 1984 was balancing the risks against what it considered to be very high benefits due to a lack of suitable alternatives, the "acceptable" level of risk now that there are suitable alternatives should be much lower than what it was in 1984, and the additional

only extremely high risks to the relatively small population of wood treatment and utility workers, but also found, in EPA's own words, "unacceptable" risks to the very large population of children who are exposed to the soil around utility poles and to penta in treated wood, in drinking water and in food. These risks to children were up to 220 times EPA's threshold for unreasonable risk. Even if risks of this magnitude could ever be justified by economic benefits, this is no longer an issue, since economically viable alternatives are now available.

With regard to suspension, the courts have cautioned that the concept of "imminent hazard," "is not limited to a crisis: 'It is enough if there is a substantial likelihood that serious harm will be experienced during the year or two required in any realistic projection of the administrative [cancellation] process." Love v. Thomas, 858 F.2d at 1350, n.3, quoting EDF v. EPA, 465 F.2d at 540. The term "emergency" is not defined in the statute, but the courts have ruled, based on EPA's own policy statements, that an emergency suspension is appropriate when there is a "substantial likelihood that serious harm will be experienced during the three or four months required in any realistic projection of the administrative suspension process." Dow Chemical Co. v. Blum, 469 F. Supp. 892, 902 (E.D. Mich. 1979)(citations omitted); Nagel v. Thomas, 666 F. Supp. 1002, 1005 (W.D. Mich. 1987)("EPA has interpreted the term [emergency] to mean a threat of harm to humans and the environment so immediate that the continuation of pesticide use is likely to result in unreasonable adverse effects during a suspension hearing."); NCAMP v. EPA, 867 F. 2d at 644 (footnote omitted)("The extraordinary step of emergency suspension is available only if the requisite unreasonable harm would be likely to

risks identified should push the scale even further in the direction of immediate action.

materialize during the pendency of ordinary suspension proceedings."). Moreover, the consideration of whether to issue a suspension or emergency suspension of a pesticide should be made in the light of "the Congressional intent [in FIFRA] that potentially dangerous pesticides should be removed form the market without delay . . .". <u>Dow Chemical v. Blum</u>, 469 F. Supp. at 900.

There can be no doubt that unreasonable harm would be likely to materialize from the continued use of penta, even in the few months it would take to hold a suspension hearing, and to a much greater degree in the year to two years or more that would be consumed by a cancellation hearing. Groundline remediation applicators and other workers, including members of plaintiff CWA, would continue to receive new exposures to penta, at extreme risks to their lives and health. Over a million newly penta-treated utility poles are installed to replace existing poles every year⁴⁹ (over a third of a million in the four months likely required for a suspension hearing), and in addition large numbers of new poles are installed where there were none before as utility services are extended to new buildings. These newly treated poles are the most hazardous to the workers who come in contact with them and to the public, as EPA has found that the major portion of the leaching of penta and its toxic contaminants into the surrounding soil occurs within the first year of application to the wood.⁵⁰

 $^{^{49}}$ EPA estimates that 3% of utility poles are replaced each year with poles newly treated with penta. EPA Penta Science Chapter at 24-25, Exhibit 3. Based on Beyond Pesticides' estimate of 52 million utility poles treated with penta, approximately 1.56 million poles would be replaced each year. Using EPA's estimate, based on older data, that there are 36 million pentatreated poles in the nation, approximately 1.08 million would be replaced each year. See Statement of Facts, p. 3, \P 2 and n. 4, *supra*.

⁵⁰ EPA Penta Science Chapter at 31, Exhibit 3.

Thus, emergency suspension action is required to prevent the treatment and installation of hundreds of thousands of new and replacement utility poles, which would pose high risks to children from exposure to soil around the poles, as well as posing extreme risks to workers who manufacture the penta, pressure-treat the wood, install and service utility poles and perform reapplications of penta to the poles. If sale and use of penta were to cease, the entire cycle of exposure to new penta, from its manufacture, its application to the wood, to the installation, use and retreatment of utility poles, to the reuse of the treated wood when the poles are taken out of service (often by unsuspecting users), to its final disposal, will be avoided.⁵¹

Equally important, there is no justification for introducing more penta into the environment when safer alternatives are available. EPA's failure to act to prevent further use of penta violates FIFRA's statutory mandate to EPA to protect the public from "unreasonable adverse effects" and from "imminent hazards," and to remove potentially dangerous pesticides from the market "without delay." It is not only illegal, but unconscionable, for EPA first to ignore evidence of viable alternatives to a pesticide which EPA found merited cancellation but for the lack of alternatives 18 years ago, and then to find dramatically high cancer risks to workers and children in a draft report, and do nothing to finalize the report or to take appropriate action in the following three years. Because EPA has failed to provide both the permanent protection of cancellation of a pesticide causing unreasonable adverse effects and the interim protection from an

 $^{^{51}}$ See, Statement of Facts, pp. 3-4, $\P\P$ 2-3 and p.9 $\P11$, supra; "Poison Poles," Exhibit 5, at 8-24.

"imminent hazard" required by FIFRA, the court should order EPA to do so. 52

2. Plaintiffs and the Public Would Suffer Irreparable Injury Absent an Injunction

The threats to human life and health posed by the continued use of penta are the essence of irreparable injury, which no judicial remedy can compensate. *See*, Henderson v. Bodine Aluminum, Inc., 70 F.3d 958, 961 (8th Cir. 1995)("preliminary injunctions become easier to obtain as the plaintiff faces progressively graver harm."). In fact, the very purpose of EPA's suspension power is to prevent serious and irreparable environmental damage. EDF v. EPA, 465 F.2d at 533. Thus, the failure to exercise that power when the statutory standards are met allows that serious and irreparable harm to occur. *See*, EDF v. Hardin, 428 F.2d at 1099 (when a pesticide poses an "imminent hazard," "even a temporary refusal to suspend results in irreparable injury on a massive scale.").

With specific regard to the use of penta, once wood is treated with penta and put into service as utility poles, the Court would have no power or ability to restore the status quo. The

be viewed as a mandatory injunction, to which a higher standard has been applied in this Circuit. Howard v. Evans, 193 F. Supp.2d 221, 226, n.3 (D.D.C. 2002). But see, United Food & Commercial Workers Union v. Southwest Ohio Regional Transit Authority, 163 F.3d 341, 347-48 (6th Cir. 1998)(rejecting application of different legal standards to mandatory and prohibitory injunctions). However, while the injunction sought here superficially appears mandatory, its effects would be prohibitory. It would require EPA take action prohibiting the further introduction of penta into the environment. The definition of a mandatory injunction is one which changes the status quo rather than preserves it. Howard v. Evans, 193 F. Supp. 2d at 226, n.3. This injunction would 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. Regardless of which legal standard applies, plaintiffs make the higher showing which may be required for a mandatory injunction, namely "showing clearly that [they] are entitled to relief or that extreme and very serious damage will result from the denial of the injunction." Id. (internal quotations and citation omitted).

treated poles will stay in use for decades, and some of the more persistent constituents of penta will remain in the environment indefinitely, posing a continual hazard to humans and the environment. Moreover, the continuing exposures to workers in the course of the manufacture of penta, the treatment and retreatment of the wood, and the installation and maintenance of utility poles could not be undone.

3. An Injunction Would Not Substantially Injure Other Parties

While the harm to plaintiffs and the public from the continued use of penta would be irreparable, little or no harm would occur to other parties from stopping its use pending this Court's consideration of the merits. Viable substitutes exist for all of penta's uses which will minimize any damage from the unavailability of penta while an injunction is in force.⁵³

If plaintiffs are not successful on the merits, the status quo permitting the use of penta can be easily restored. Even if plaintiffs are successful on the merits, interested parties have a statutory right to request cancellation and suspension hearings at EPA, where all of the issues concerning the risks and benefits of any future use of penta will be explored in depth, and the prohibition on penta's use can be reversed or modified.

Moreover, the only kind of injuries that could be caused by halting penta's use would be in the nature of inconvenience or monetary loss, as opposed to the threats to life and health that are posed by continued use. Pesticides are by their nature poisons with potential harmful impacts on human health and the environment, and Congress determined in FIFRA that "potentially

⁵³ See, Affidavits of Robert G. J. Jack and Joseph W. Reilly, Exhibits 1 and 2; "Poison Poles," at 33-36, Exhibit 5; "Petition for Suspension and Cancellation of Pentachlorophenol," at 11-12, Exhibit 16.

dangerous pesticides should be removed form the market without delay . . .". <u>Dow Chemical v.</u> <u>Blum</u>, 469 F. Supp. at 900. Thus, inherent in the statutory scheme is an expectation that some injury will be borne by users of pesticides which are canceled or suspended, for the greater good of protecting human health and the environment.⁵⁴ Because the standards for cancellation and suspension themselves require a balancing of environmental, economic and social costs and benefits, if plaintiffs are correct on the merits, *i.e.*, that the standards for cancellation and suspension are met by EPA's own findings, then by definition, the balance of harms favors the plaintiffs.⁵⁵

4. An Injunction Would Further the Public Interest

The public interest in avoiding additional exposure to a chemical which causes cancer, birth defects, and other adverse health effects is too obvious to belabor. With the advent of economically viable alternatives which do not pose these risks, there is little or no disadvantage to the public from stopping the use of penta. In fact, EPA's failure to take action to cancel penta's

Because FIFRA's registration standard refers to the "economic, social, and environmental costs and benefits of the *use* of any pesticide," 7 U.S.C. § 136(bb)(emphasis supplied), EPA has determined that in its cancellation and suspensions decisions it need consider only "economic impacts on pesticide users and the consumers of the products of the users. The impacts on pesticide *manufacturers* are not germane to this type of regulatory decision, in which the risk of the use of a pesticide is compared to the benefits of those uses." (Emphasis supplied.) "Intent to Cancel Registrations of Pesticide Products Containing Creosote and Coal Tar for Nonwood Purposes," 50 Fed. Reg. 41943, 41948 (Oct. 16, 1985).

⁵⁵ As explained above, it is not necessary to explore or determine the balance of environmental, economic and social costs and benefits in the context of this court proceeding, because EPA has already done so, determining that the hazards of penta warrant cancellation for any use for which economically viable alternatives are available. EPA has also made findings concerning the hazards of penta which meet the statutory standards for suspension and emergency suspension.

registration actually serves to constrain the ability of the manufacturers, distributors and vendors of more environmentally benign products (such as utility poles made of fiberglass or steel) to market their products, because of the imprimatur that EPA's registration lends to penta-treated poles and utilities' consequent reluctance to switch to alternatives. In effect, EPA is in the ironic position of tilting the playing field in favor penta by maintaining its registration when non-toxic alternatives are available at competitive cost and would emerge in a fair marketplace. EPA's registration sends the inaccurate message to the marketplace that penta is "safe" and should compete equally with other products including those that are non-toxic.

Congress has enacted a law which mandates protection of the public from pesticides posing the types of risks posed by penta, and the Court may assume that proper implementation of the statute serves the public interest. *Cf.*, Government of the Virgin Islands v. Virgin Islands

Paving, Inc., 714 F.2d 283, 286 (3rd Cir. 1983)("The enactment of a comprehensive regulatory scheme is a reflection of the Legislature's view of the importance of the interests at stake.").

CONCLUSION

For the foregoing reasons, the Court should grant a preliminary injunction to compelling defendant Christine T. Whitman, in her capacity as EPA Administrator, to issue a notice of cancellation of the registrations of all products containing penta intended for use as wood preservatives, pursuant to 7 U.S.C. § 136d(b)(1), and at the same time to issue an emergency order pursuant to 7 U.S.C. § 136d(c)(3) to suspend immediately those registrations. A proposed order granting the requested relief is attached.

Respectfully submitted,

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BEYOND PESTICIDES v. WHITMAN

APPENDIX A TO PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Chronology of EPA's Review of the Wood Preservative Pesticides

- 1. Beginning in 1978, because of incident reports and scientific studies suggesting adverse effects including cancer, genetic mutations and birth defects, EPA began a regulatory review known as the Rebuttable Presumption Against Registration, ("RPAR") to evaluate the acceptability of continued registration of the wood preservatives creosote, penta, and inorganic arsenicals. The RPAR proceeding was initiated when EPA made findings that these three wood preservative pesticides exceeded the regulatory risk levels that would trigger cancellation of a pesticide's registration under FIFRA's continuing requirement that pesticides "not generally cause unreasonable adverse effects on the environment." EPA found that penta (or its contaminants) caused defects in the offspring of laboratory animals. Under the RPAR process, the pesticides would be canceled unless information submitted by the registrants rebutted the presumption that these pesticides did not meet the registration standard.
 - 2. On February 19, 1981, EPA published its Preliminary Determination concluding the

¹ 43 Fed. Reg. 48154 (Oct. 18, 1978). EPA issued separate RPAR notices for creosote, 43 Fed. Reg. 48154, inorganic arsenicals, 43 Fed. Reg. 48267, and penta, 43 Fed. Reg. 48443. However, EPA determined to consider all three of these wood preservatives together in the risk-benefit part of the RPAR review process. 43 Fed. Reg. 48154.

² Former 40 C.F.R. § 162.11. The RPAR for the wood preservatives was completed under the current Special Review regulations, which are found at 40 C.F.R. § 154.1 *et seq*.

³ "Creosote, Pentachlorophenol and Inorganic Arsenicals; Intent to Cancel," 49 Fed. Reg. 28666, 28667 (July 13, 1984) "Unless all presumptions of risk are rebutted, the RPAR is concluded by issuance of a Notice of Intent to Cancel."

RPAR. 46 Fed. Reg. 13020. EPA determined that "the information submitted to overcome the risk concerns ... for the wood preservative pesticide chemicals was insufficient to overcome the presumption against these chemicals for the effects of concern." *Id.* at 13023. In addition, based on information received since the RPAR was issued, EPA determined that penta posed cancer risks because of the presence of dioxin contaminants, which also had the potential to produce teratogenic/fetotoxic (birth defects or fetal toxicity) effects. *Id.* at 13021. EPA found that exposure to penta for treatment plant workers posed lifetime cancer risks as high as 1 in 100 (1 x 10-2) from inhalation and dermal exposure, including the handling of treated wood. EPA noted that there were also risks to the users of treated wood from dermal contact. *Id.*, at 13023.

EPA stated that it was "very concerned about reducing the possible high risks to [wood] treatment plant workers," but in order to reduce the risks to workers, EPA asserted that it would have had to cancel all three of the wood preservatives because elimination of one would lead to substitution with one of the others. EPA claimed that: "Due to the non-substitutability of the wood preservative compounds and the lack of acceptable non-wood or other chemical alternatives for many use situations, the economic impact which would result from across-the-board cancellation would be immense." *Id.*, at 13032. Therefore, EPA determined to retain the registrations of all three wood preservatives if its proposed risk reduction measures were adopted.

3. After evaluating comments from its Scientific Advisory Panel, the Secretary of Agriculture and interested parties, on July 13, 1984, EPA issued its notice concluding the RPAR process. 49 Fed. Reg. 28666. EPA adopted its 1981 preliminary determination, which it described as follows: "In light of the very high economic benefits resulting from the use of the wood preservative chemicals, the Agency determined that the use of the wood preservative

chemicals in accordance with the [] modifications [proposed in 1981] would be expected to satisfy the statutory standard for registration." *Id.* After reevaluating the available data, EPA concluded with regard to penta that "the Agency's conclusions regarding the risks posed by the wood preservative chemicals remain intact." *Id.* at 28668.

EPA adopted the risk reduction measures proposed in 1981 with some modifications. These measures included restricting the sale and use of penta, creosote and arsenical wood preservatives to certified applicators, a requirement for protective clothing and the use of respirators in high exposure situations, and a requirement that the manufacturers of penta reduce the levels of dioxin to less than one part per million within 18 months. EPA required a warning label on penta wood preservative products stating that "The U.S. EPA has determined that pentachlorophenol can produce defects in the offspring of laboratory animals. Exposure to pentachlorophenol during pregnancy should be avoided." *Id.* at 28673.⁴

- 4. In its July 11, 1984 press statement describing the decision and the risk reduction measures it was requiring of the wood preservative registrants, EPA said, "without these restrictions, the risk to public health from using these pesticides would outweigh the benefits." Exhibit 8.
- 5. As a result of requests for administrative hearings on the 1984 risk reduction measures, EPA stayed their effective date. After negotiations with the parties to the hearings, EPA published a modified set of risk reduction measures in 1986. 51 Fed. Reg. 1334 (Jan. 10, 1986).
 - 6. On January 2, 1987, EPA issued a notice amending the risk reduction measures

⁴ This warning is affixed to the chemicals used to treat wood, not to the treated wood products to which consumers are exposed.

adopted in 1986. As a result of a settlement with two registrants, EPA increased the levels of dioxin and other contaminants of penta permitted by the 1986 Amended Notice, which levels EPA had previously said were necessary to reduce the risk to levels such that benefits would outweigh the risks. 52 Fed. Reg. 140.

- 7. Between 1987 and 1993 EPA cancelled the registrations of penta for all uses other than as wood preservatives because of excessive risk.⁵
- 8. EPA's most current assessments and statements concerning penta, including the 1999 EPA Penta Science Chapter discussed in the text, not only to affirm the risk findings made in the RPAR process, but also to add risk concerns. A "Hazard Summary" for penta currently on EPA's web site states that penta is "extremely toxic to humans" and a "probable human carcinogen." EPA has set the Maximum Containment Level Goal for penta in drinking water as zero, because EPA believes this is required to prevent damage to the central nervous system from short-term exposure and reproductive effects, damage to liver and kidneys and cancer from long-term exposure. An EPA "Product Matrix" on "Wood Preservatives" states that penta has "been shown to cause cancer . . . in lab animals. In addition, . . . pentachlorophenol is associated with birth defects and fetal toxicity." In 2001, the Department of Health and Human Services

⁵ 58 Fed. Reg. 7848 (Feb. 9, 1993) (cancellation of last remaining non-wood uses of penta).

⁶ "Pentachlorophenol 87-86-5," U.S.E.P.A., available at http://www.epa.gov/ttnatw/hlthef/pentachl.html.

⁷ "National Primary Drinking Water Regulations, Consumer Fact Sheet on: Pentachlorophenol," available at www.epa.gov/safewater/dwh/c-soc/pentachl.html.

⁸ "Product Matrix - Wood Preservatives," available at http://www.epa.gov/grtlakes/seahome/housewaste/house/woodpre.htm.

upgraded the classification of dioxin, which is a contaminant of penta, from a "reasonably anticipated" to a "known" human carcinogen. *See*, <u>Tozzi v. U.S. Dept. of Health and Human Services</u>, 271 F.3d 301 (D.C. Cir. 2001).

BEYOND PESTICIDES, et al. v. WHITMAN

APPENDIX B TO PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR PRELIMINARY INUNCTION

Chronology of Petitions to Cancel and Suspend Penta's Registration

- 1. On June 2, 1997, Dr. Howard Freed, M.D. and a group of eleven other noted public health scientists and physicians, including members of Beyond Pesticides, wrote to EPA calling attention to studies that found wood preservatives in the "body fluids and tissues of humans in the general population," which raised concern because of these chemicals' "association with cancer, birth defects, [and] disruption of the endocrine system...". The scientists referred to the information on alternatives in Beyond Pesticides' "Poison Poles" report (Exhibit 5), and pressed the Agency to begin immediately a reassessment of treated wood and its alternatives, and "as quickly as possible... to curtail the introduction of these chlorinated hydrocarbons [penta] into the environment...". Exhibit 9.
- 2. On July 9, 1997, Dr. Lyn Goldman, Assistant Administrator for EPA's Office of Pollution Prevention and Toxic Substances ("OPPTS") replied, assuring the scientists and public health officials that their concerns were being addressed. She specified a timetable in which EPA expected to complete the Registration Eligibility Decision ("RED") on penta:

Penta and all of the currently registered wood preservatives will be reassessed as part of EPA's ongoing reregistration program, which was established by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Amendments of 1988. As part of the reregistration review, EPA is requiring manufacturers (registrants) to submit additional data, including exposure data on wood treatment plant employees and the general population. Once the required studies are submitted, EPA will complete its analyses and issue a Reregistration Eligibility Decision (RED) on the continued use of pentachlorophenol on wood utility poles. A RED on penta is expected in FY 1998 by OPP's new Antimicrobial Division,

which is currently hiring more scientists to perform reregistration reviews. This analysis will include additional consideration of the chemical's impact on human health and potential endocrine disruption effects.

In response to the scientists' submission on the use of alternative materials instead of treated wood, the letter stated: "After the Agency completes the penta RED, it may make sense to carry out such a reassessment." Exhibit 10.

- 3. When the RED for penta had yet to be issued in February of 1999, Beyond Pesticides sought and was granted a meeting with Frank T. Sanders, director of EPA's Antimicrobial Division and his staff. Beyond Pesticides was informed that the penta RED was only in its draft stages, and the preliminary science chapter would not be available for public review until late 1999. The EPA representatives promised to share their preliminary findings with the public.
- 4. EPA released its draft Science Chapter for the penta RED to the wood treatment industry in the early summer of 1999. Beyond Pesticides obtained a copy in September, 1999. EPA found extremely high risks from the wood preservative use of penta to children and to workers, including a more than 100% lifetime risk of cancer for one category of workers. Exhibit 3.
- 5. On December 21, 1999, Beyond Pesticides submitted comments on the EPA Penta Science Chapter to EPA. Exhibit 11. The comments called for cancellation of penta's registration. With the comments, Beyond Pesticides transmitted a copy of its report entitled "Pole Pollution New Utility Pole Chemical Risks Identified by EPA While Survey Shows Widespread Contamination." Exhibit 7.
 - 6. On July 21, 2000, David C. Vladeck, of the Public Citizen Litigation Group, wrote to

the EPA administrator on behalf of Beyond Pesticides, making a "formal request to the agency to initiate a proceeding to cancel the remaining registration for Penta as a wood preservative." The letter recounted the history of Beyond Pesticides' efforts to have EPA remove penta from the market and summarized and resubmitted Beyond Pesticides' 1997 "Poison Poles" and 1999 "Pole Pollution" reports. The letter stated that EPA's failure to reassess penta in accordance with its previous commitments was in violation of the Administrative Procedure Act and of FIFRA. It further stated that rather than bring a court action at that time, Beyond Pesticides preferred to work with EPA, and was therefore renewing and supplementing its 1997 requests. The letter concluded by asking for a response within 30 days including EPA's projected timetable for action on penta. Exhibit 12.

- 7. On September 8, 2000, EPA responded to Mr. Vladeck's letter in a letter signed by Acting Assistant Administrator Susan H. Wayland. EPA's letter acknowledged Beyond Pesticides' request to cancel penta's registration, and stated that the agency expected to finish the risk assessment on penta and begin the public review process in 2001. Exhibit 13.
- 8. Since that September, 2000 letter, EPA has not given any public indication of any progress on its assessment of penta, nor issued the RED originally promised for 1998.
- 9. On April 19, 2001 Beyond Pesticides wrote to EPA requesting cancellation and emergency suspension of penta, CCA and creosote. The letter noted that "EPA's current review, which has dragged on since 1998 and is expected to continue through 2003, is unacceptable in meeting the urgent need to protect children from daily exposure to known human carcinogens, endocrine disruptors and highly neurotoxic chemicals." The letter stated that there were

alternatives to treated wood for utility poles and other uses. Exhibit 14.

- 10. EPA responded to Beyond Pesticides' April, 19, 2001 petition for cancellation and emergency suspension in a letter dated May 16, 2001 signed by Stephen L. Johnson, Acting Assistant Administrator for OPPTS. EPA's letter explained that the Agency was "currently reassessing CCA, pentachlorophenol and creosote as part of the Agency's ongoing effort to ensure that older pesticides meet current safety standards." Mr. Johnson assured Beyond Pesticides that "We are giving this priority attention." No timetable was offered for completion of these assessments. Exhibit 15.
- 11. On December 21, 2001, Beyond Pesticides and several other organizations again petitioned EPA seeking immediate suspension and cancellation of penta based on EPA's previous findings in the 1978 RPAR as well as new evidence of risk from these pesticides and additional information about available alternatives to penta-treated wood that had been submitted to EPA by Beyond Pesticides and others. The petition also requested a consumer awareness program for reused wood products treated with penta. Exhibit 16.
- 12. On March 5, 2002 EPA responded to Beyond Pesticides December 21, 2002 petitions for cancellation and suspension of CCA and penta in a letter signed by Assistant Administrator Stephen L. Johnson, stating, "this interim reply to your petition constitutes neither a denial nor an acceptance of your petition." The letter stated that the wood preservative pesticides were undergoing reregistration review and that the agency was "proceeding as rapidly as feasible to resolve your concerns." It offered no timetable for completion of review. Exhibit 17.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

BEYOND PESTICIDES/ NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES, et al.,

Plaintiffs,

CHRISTINE T. WHITMAN, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY, et al.,

Defendants.

EXHIBITS TO MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

- 1. Affidavit of Robert G. J. Jack, dated September 6, 2002
- 2. Affidavit of Joseph W. Reilly, dated August 29, 2002
- 3. U.S. Environmental Protection Agency, 1999. "Science Chapter for the Reregistration Eligibility Decision Document (RED) for Pentachlorophenol" (PC Code: 063001, Registration Case Number 2505)
- 4. American Wood Preservers Institute, 1996. "The 1995 Wood Preserving Industry Protection Statistical Report" (Excerpts).
- 5. National Coalition Against the Misuse of Pesticides, 1997. "Poison Poles A Report About Their Toxic Trail and Safer Alternatives."
- 6. United Nations, Fifth Issue, 1994. "Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by

Governments." (Excerpts)

- 7. Beyond Pesticides/National Coalition Against the Misuse of Pesticides, December, 1999. "Pole Pollution – New Utility Pole Chemical Risks Identified by EPA While Survey Shows Widespread Contamination."
- 8. Environmental News, "EPA Restricts Uses of Wood Preservatives," July 11, 1984.
- 9. Letter to Carol Browner, Administrator, U.S. EPA from Howard Freed MD, *et al.* dated June 2, 1997.
- Letter to Howard Freed, MD from Lynn Goldman, Assistant Administrator, EPA, dated July
 1997.
- Public Comments in Response to Reregistration Eligibility Decision, Pentachlorophenol, Case
 Beyond Pesticides, National Coalition Against the Misuse of Pesticides, December 21,
 1999.
- 12. Letter to Carol Browner, Administrator, EPA from David C. Vladeck, Public Citizen Litigation Group, dated July 21, 2000.
- 13. Letter to David C. Vladeck from Susan H. Wayland, Acting Assistant Administrator, EPA, dated September 8, 2000.
- 14. Letter to Christine T. Whitman, Administrator, EPA from Jay Feldman, Executive Director, Beyond Pesticides/National Coalition Against the Misuse of Pesticides, dated April 19, 2001
- 15. Letter to Jay Feldman, Executive Director, Beyond Pesticides/National Coalition Against the Misuse of Pesticides, from Stephen L. Johnson, Acting Assistant Administrator, EPA, dated May 16, 2001.

- 16. Petition for Suspension and Cancellation of Pentachlorophenol, Beyond Pesticides/National Coalition Against the Misuse of Pesticides, *et al.*, December 21, 2001.
- 17. Letter to Jay Feldman, Executive Director, Beyond Pesticides/National Coalition Against the Misuse of Pesticides, from Stephen L. Johnson, Assistant Administrator, EPA, dated February 5, 2002.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

BEYOND PESTICIDES/ NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES, et al.,

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	Civil Action No.
V	Civil Action No.

CHRISTINE T. WHITMAN, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY, et al.,

Defendants.

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Plaintiffs' Motion for a Preliminary Injunction,
Plaintiffs' Memorandum of Points and Authorities in Support of Motion for Preliminary
Injunction, with Appendices and Exhibits, Plaintiffs' Request for Expedited Hearing, and
Plaintiffs' Request to Defendants Whitman and the Environmental Protection Agency for the
Production of Documents, or Alternatively, for Submission of the Administrative Record were
served by hand delivery by messenger service this 10th day of December, 2002, upon the
following:

Christine T. Whitman, Administrator, United States Environmental Protection Agency 1101A, Ariel Rios Building, 1200 Pennsylvania, Ave, N.W. Washington, D.C. 20460

Mark Nagel, Chief, Civil Division U.S. Attorney for the District of Columbia 555 4th Street, N.W. Washington, D.C. 20530

John Ashcroft, Attorney General of the United States
Department of Justice
950 Pennsylvania Ave., N.W.
Washington, D.C. 20530

Paula Dinerstein