IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BEYOND PESTICIDES/NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES 701 E. Street, SE Washington, D.C. 20003 Plaintiffs, v. CHRISTINE T. WHITMAN, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Ariel Rios Building, 1101A 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 Defendant.	)	Case Number: 1:02CV02419 (RJL)

DECLARATION OF JACK E. HOUSENGER

In accordance with 28 U.S.C. § 1746, Jack E. Housenger hereby declares as follows:

1. I am the acting Associate Director of the Antimicrobials Division (AD) in the Office of Pesticide Programs (OPP) in the Environmental Protection Agency. I have been in this position since May 2002 and previously held the position of Associate Director of the Special Review and Reregistration Division (SRRD) since 1996.

2. The Office of Pesticide Programs (OPP) is responsible for administering EPA's statutory responsibilities for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136 et seq., and the Federal Food, Drug, and Cosmetic Act ("FFDCA") , 21 U.S.C. §§ 301 et seq.

3. Under section 4 of FIFRA, 7 U.S.C. § 136a-1, EPA is required to reregister each registered pesticide containing an active ingredient first registered before November 1, 1984. OPP administers pesticide reregistration for EPA.

4. OPP is also responsible for conducting EPA's Special Review program pursuant to 40 C.F.R. Part 154, formerly known as the Rebuttable Presumption Against Registration (RPAR) process. The RPAR process was created by the Agency in 1975 to provide a process whereby EPA could evaluate whether or not a pesticide met the standard for registration without having to go through adjudicatory proceedings (i.e. cancellation action).

5. The Antimicrobials Division is responsible for the registration and reregistration activities for all antimicrobial pesticides as well as products that are used as wood preservatives. Among the Division's regulatory responsibilities are such diverse and critical programs as registration and reregistration of hospital disinfectant products and approval of agents for the bioremediation of anthrax contamination and other counter-bio-terrorism efforts. For instance, AD, along with other OPP programs, was instrumental in the coordinated government response to the 2001 terrorist incidents of anthrax contamination in Washington D.C. and elsewhere.

Pesticide Reregistration

6. Under the reregistration program within OPP, pesticides which were registered prior to November 1, 1984 are evaluated to ensure that they continue to meet current safety standards. EPA began this effort in response to the 1988 amendments to FIFRA. In general, this evaluation process involves comprehensive data collection and a thorough review of all available information on a pesticide to evaluate potential risks and benefits associated with the pesticide. Evaluating the risks associated with a pesticide involves determining the exposure to the

pesticide, including exposure from the mixing/loading and application of the pesticide, dietary ingestion (from food and water, if necessary), any non-dietary non-occupational exposures (for example to children playing on wood treated with a wood preservative), and risks posed to aquatic and terrestrial organisms. The benefits resulting from a pesticide's use are also evaluated in light of the availability of alternatives that could achieve the pesticide's purpose, as well as the impacts on society resulting from the use of alternative pesticides or nonchemical alternatives (impacts such as higher cost of alternative pesticides, decreased availability and increased cost of crops due to increased pest damage, etc.). The risks posed by the alternatives that might replace the subject pesticide are also assessed qualitatively and considered. The estimated risks are then compared to the estimated benefits and a decision is made whether the pesticide meets the statutory standard for registration.

7. The reregistration process is laid out in five phases in FIFRA § 4, with time frames and specific responsibilities for each phase.

a. Phase 1 - List Active Ingredients - As required, EPA published Lists A, B, C, and D within 10 months of FIFRA '88 (by October 24, 1989) and asked registrants of these pesticides whether they intended to seek reregistration. There are 612 reregistration "cases," where a "case" represents one or multiple related pesticide active ingredients. Because EPA had already substantially reviewed them under the Registration Standards program, the List A pesticides moved directly to Phase 5, and the List B, C, and D pesticides went on through the other four phases.

b. Phase 2 - Declare Intent and Identify Studies - Phase 2 required registrants to notify EPA whether or not they intended to reregister their products; to identify and commit to

providing necessary new studies; and to pay the first installment of the reregistration fee. During this phase, EPA issued guidance to registrants for preparing their Phase 2 and Phase 3 responses. Phase 2 activities were completed in 1990.

c. Phase 3 - Summarize Studies - During Phase 3, following EPA guidance, registrants were required to submit summaries and reformat acceptable studies, "flag" studies indicating adverse effects, re-commit to satisfying all applicable data requirements, and pay the final installment of the reregistration fee. Phase 3 ended in October 1990.

d. Phase 4 - EPA Review and Data Call-In - During Phase 4, EPA reviewed all Phase 2 and 3 submissions and required registrants to meet any unfulfilled data requirements within four years. Phase 4 was completed in 1993.

e. Phase 5 - Reregistration Decisions - In this final phase, EPA reviews all the studies that have been submitted for a case, and decides whether pesticide products containing the active ingredient(s) are eligible for reregistration -- whether the data base is substantially complete, and whether the pesticide causes unreasonable adverse effects to people or the environment when used according to product labeling. EPA also considers whether the pesticide meets the new safety standard of the 1996 Food Quality Protection Act. The results of the Agency's review are presented in a Reregistration Eligibility Decision (RED) document. Products containing the pesticide are reregistered after certain product-specific data and revised labeling are submitted and approved. This decision may include findings that regulatory measures are needed to adequately reduce the pesticide's risks (ranging from cancellation to requiring protective clothing to no action required). Section 4 directs that, if EPA determines a pesticide is not eligible for reregistration, EPA "shall take appropriate regulatory action." 7 U.S.C. § 136a-1(g)(2)(D).

8. Since 1988, OPP has issued 214 REDs for one or more pesticide active ingredients (some REDs cover more than one related active ingredients) which are contained in thousands of registered pesticide products. The first RED was issued in 1991. There are 167 REDs in progress in OPP. It can take anywhere from 8 months to several years to complete a reregistration decision, depending on the amount of data to be reviewed and the complexity of the issues presented.

9. OPP has established a public participation process for reregistration activities. This process was developed in 1998 as a pilot for the organophosphate pesticides out of discussions with various stakeholders through an advisory committee called the Tolerance Reassessment Advisory Committee (TRAC). The first step in this process is for EPA to review the database for a pesticide, require development and submission of any additional necessary data, and draft a preliminary assessment of health and environmental risks for the registered uses of the pesticide. The preliminary risk assessment is the Agency's first estimate of how much risk is presented by exposure to a pesticide. This estimate considers how toxic a pesticide is (i.e. what effects the pesticide causes and at what doses) and how much exposure to the pesticide humans and other non-target organisms would experience (e.g., whether people would inhale, ingest, or absorb residues of the pesticide, and how much). By multiplying the exposure quantity by the toxicity level, scientists can get an idea of how likely it is that an exposure would result in adverse effects.

10. Second, the draft preliminary risk assessment is sent to the pesticide's registrants who submitted the data on which the assessment is based for the registrant to review for a brief period (thirty days) just to ensure that the Agency has not made any technical errors such as

computational mistakes. After receiving comments from the registrants, OPP revises the draft preliminary risk assessment as necessary. The OPP makes it available to the public for comment (usually about 60-90 days after receiving comments from the registrants), both on the world wide web and in the docket at EPA headquarters. This comment period is generally sixty days.

11. Third, OPP considers all the comments submitted by the public and revises the risk assessment as needed and develops a revised risk assessment. The revised risk assessment is then made available for the public, both on the world wide web and in the docket at EPA Headquarters, and public comment is solicited on risk management options and ideas.

12. Finally, OPP incorporates the final risk assessment into a RED document which considers both the risks and benefits of the pesticide. Included in this analysis is a qualitative consideration of the risks posed by alternatives that might replace the subject pesticide in the marketplace. OPP then makes a determination as to whether the pesticide meets current standards, i.e. does not pose unreasonable adverse effects to the environment, taking into consideration the comments that were received on risk management.

13. The Agency has also employed a shortened public participation process which eliminates the second public comment period. In these instances, EPA has been very diligent to solicit ideas and options on risk mitigation measures through conference calls and meetings with interested stakeholders.

EPA's Evaluation of Pentachlorophenol

14. Pentachlorophenol ("penta") is a pesticide which is used as a wood preservative and which has been registered under FIFRA since 1948. It is used almost exclusively for the treatment of utility poles, but its other uses include treatment of wood used as crossarms, lumber,

fencing, posts, shingles, steps, walkways, piers, docks, and bridges.

15. The Agency's first evaluation of potential carcinogenic, fetotoxic and developmental risks from exposure to penta began in 1978 under the Rebuttable Presumption Against Registration (RPAR) Process (now the Special Review process). As part of that process, OPP conducted a detailed assessment of the risks and benefits of three wood preservative pesticides, penta, inorganic arsenicals, and creosote, and in 1981 issued a set of preliminary findings that the risks of the wood preservatives were high enough to warrant regulatory restrictions in order to maintain their registrations. OPP chose to examine all three types of preservatives at the same time because cancellation of any one active ingredient or any use of an active ingredient would likely lead to substitution with the other two, which might not reduce overall risk to the public and environment. EPA took comments on these preliminary findings, held a public meeting, took additional comments after the meeting, and evaluated the information submitted by the public to refine the assessments of the risks and benefits of the wood preservatives.

16. In 1984, OPP concluded the RPAR process by issuing a Notice of intent to cancel the registrations of the three wood preservatives. This Notice found that unless the pesticide registrants made certain modifications to the products and the registrations, the risks associated with these three pesticides outweighed the benefits. Several trade associations and registrants of the wood preservatives requested an adjudicatory hearing on the Notice of Intent to Cancel pursuant to FIFRA § 6(b).

17. EPA negotiated a settlement with several of the major parties who had requested hearings which averted the need to hold a lengthy and costly hearing. As a result of this settlement, in 1986, the registrants of the wood preservative products were required to adopt risk

reduction measures intended to bring their products into compliance with the FIFRA standard for registration. In 1987 OPP imposed new limitations on allowable levels of contaminants, namely hexachlorobenzene (HCB) and certain dioxins which could be present in products containing penta.

18. OPP began reregistration of the wood preservatives in 1997. Like it did for the 1978 RPAR, OPP has been conducting its review of the three wood preservative active ingredients together to ensure that any regulatory action will consider the potential impacts of substitution with the other active ingredients. Because of the high toxicity of these active ingredients, it is possible to inadvertently create a greater risk than was present before by imprudently taking regulatory action on one pesticide at a time.

19. In 1999, as one step in this reregistration process, OPP developed a draft of a preliminary risk assessment for penta. This assessment was conducted only for penta and did not include any consideration of the risks posed by penta's HCB or dioxin contaminants. Although the draft preliminary assessment was provided to the registrants of penta and later to the public, it was never intended to be the final risk assessment for the purpose of making a reregistration decision. OPP did make this document available in the public docket, but it did not consider this release to be a part of the public participation process for developing risk assessments and REDs.

20. Between April 1999 and September 2001 AD received worker exposure studies for each of the three wood preservatives. The study on penta has been incorporated into a new draft of the preliminary risk assessment for penta (see ¶ 22 below).

21. Since the start of the reregistration process for penta and the other two wood preservatives, OPP staff have met and corresponded with various stakeholders, including

representatives of Beyond Pesticides, to discuss the progress of the Agency's review, and to receive additional information that might contribute to the review. In addition, EPA has worked with members of the regulated community and the public to further reduce risks from the wood preservatives prior to completing their reregistration review. In July 2001, EPA announced that the wood treatment industry in conjunction with EPA had developed a plan to immediately provide improved consumer safety information to users of CCA-treated wood. In February 2002, EPA announced further voluntary efforts by the industry in the form of a phase-out and cancellation of all CCA wood treatment products registered for treating wood for most residential uses (e.g. decks, picnic tables, play structures).

22. Most recently, on November 27, 2002, the Antimicrobials Division completed a new draft preliminary risk assessment for penta which is currently undergoing internal review for quality control. This preliminary assessment is based on most of the same information as the 1999 draft. It differs from the 1999 version largely by a) the incorporation of the 1999 worker exposure study which was received after the completion of the previous assessment; and b) inclusion of risk estimates for the contaminants HCB and dioxins. This risk assessment, when finalized, will be used by the Agency to complete the REDs for penta and the other two wood perservatives.

23. The current draft of the preliminary risk assessment for penta is undergoing an internal quality control step. Once this has been completed, EPA will forward the preliminary risk assessment to the technical registrants for the thirty day "error correction" comment period in EPA's public participation process for reregistration decisions noted above. It is expected that this assessment will be ready to be forwarded to the registrants of penta manufacturing use

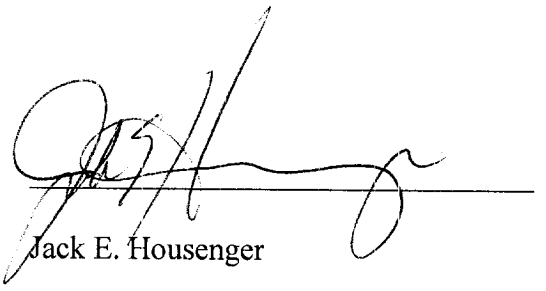
products during the month of January, 2003. EPA will incorporate any revisions necessitated by the registrants' comments, and begin the public participation process detailed above.

24. The Agency will allow either one or two public comment periods as described above, and then the Antimicrobials Division will consider the comments and determine whether any risk reduction measures are necessary to meet the FIFRA standard that no unreasonable adverse effects are presented from the use of penta. (This is done considering the benefits that are provided for through the use of penta including the risks, costs and effectiveness of alternatives.) The Agency may meet with the registrants, industry, environmental groups, or other interested stakeholders to discuss ways in which potential risks may be addressed. A final reregistration decision can then be made which will detail the potential risks associated with the use of penta, the benefits associated with the use including the risks of alternatives and the costs of these alternatives relative to penta, the risk mitigation measures (if any) that the Agency determines are necessary to maintain the penta registrations and the Agency's rationale for its decision

25. Following the issuance of the preliminary risk assessment for public comment, based on the Agency's past experience, it would be expected to take about 6-8 months to complete a RED (if the Agency takes comments on a revised risk assessment prior to the completion of a RED, it could take significantly longer). However, there are numerous foreseeable contingencies that can extend the timing, such as receiving new data or new analyses in the public comments, having new complicated scientific issues raised, and addressing difficult risk mitigation and implementation issues. In the Agency's experience, these contingencies could extend the process of completing a RED to as long as 3 years in the unusual situation.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 19th day of December, 2002.



Jack E. Housenger