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Ser 1811.ED/2937
September 24, 1993

Mr. John E. Scandura
Chief
State of California - Environmental Protection Agency
Department of Toxic Substances Control, Region 4
Federal Site Mitigation Branch
245 Broadway, Suite 350
Long Beach, CA 90802

Subj: USE OF CALIFORNIA CANCER POTENCY FACTORS FOR MARINE CORPS
BASE CAMP PENDLETON

Dear Mr. Scandura:

We appreciate Dr. John Christopher's letter of June 28, 1993 in response to my May 12, 1993 letter to you regarding use of State of California cancer potency factors in Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) work underway at Marine Corps Base (MCB) Camp Pendleton. It was very helpful.

Our immediate plan regarding this issue is to continue the "dual track analyses" using both U.S. Environmental Protection Agency (EPA) and the California EPA (Cal\EPA) cancer potency factors further into the CERCLA process while we review this issue in more depth, reserving our final decision until later in the CERCLA process. We request further assistance from you in clarifying Cal\EPA's position concerning whether the Cal\EPA cancer potency factors satisfy the statutory and regulatory criteria for State applicable or relevant and appropriate requirements (ARARs) under Section 121 of CERCLA and the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) (40 CFR Part 300). Our specific concerns are set forth below.

Please do not interpret our review of these issues as indicating a bias against utilizing the Cal\EPA cancer potency factors in the CERCLA process. Department of the Navy (DON) is obligated to look into these issues as the lead Federal agency at MCB Camp Pendleton under CERCLA, the NCP, and the Federal Facility Agreement (FFA) for the site. We would like to emphasize that even if the State cancer potency factors are "To Be Considered" (TBCs) criteria rather than ARARs, DON does not intend to categorically reject them. We want to engage in a constructive and productive dialogue involving both staff and management in our organizations.

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DON intends to thoroughly and systematically review the cancer potency factors, including their relative scientific validity, and may decide to accept them as a component of the remedial actions or to reject them based upon their appropriateness at the sites. In addition to investigating the ARARs issues, DON is in the process of reviewing the Cal\EPA potency factors in order to fully understand why cancer potency factors developed by U. S. EPA and Cal\EPA differ and to assess the potential impact of those differences on the remediation of MCB Camp Pendleton sites.

DON has yet to conclude whether or not the differences between State and Federal cancer potency factors have any practical significance. If DON's review concludes that the impact on site remediation with respect to costs, practicality, and feasibility is insignificant, this issue may resolve in adoption of Cal\EPA cancer potency factors.

To expedite formulating our position, we seek further assistance from you. The following issues are still unclear to us.

1. We request clarification as to whether the State considers the cancer potency factors to be State ARARs. The first sentence of the second paragraph of your letter states in part "... , Cal\EPA interprets its published cancer potency factors to meet the criteria for designation as potential chemical-specific "applicable or relevant and appropriate" (ARAR) criteria,...(DON emphasis supplied)". The State's intent in use of the term "potential" is unclear. In addition, in the second sentence of the second paragraph on page two of the letter, it states "Cal\EPA feels it is self-evident that its cancer potency factors are at the very least criteria 'to be considered' (TBC), as defined in the 'CERCLA Compliance with Other Laws Manual'." This sentence also raises doubt as to the State's position on this issue. Your clarification would be appreciated.

2. We would also appreciate further explanation of DTSC's position that the cancer potency factors have been "duly promulgated". More specifically, it would assist us if you would please address the following questions:

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a. Are the cancer potency factors "of general application" as set forth in Government Code §11342?

b. Does the State currently or in the future intend to attempt to directly "enforce" the cancer potency factors themselves within the meaning of Government Code §11347.5? If so, in what cases and under what authority?

c. Are the cancer potency factors "regulations" as defined in Government Code §11342?

d. Are the cancer potency factors themselves directly published in California Code of Regulations (CCR) as regulations? If so, specific citations to specific sections of the CCR would be most helpful. Our initial research has not located cancer potency factors directly published in the CCR.

3. It is our understanding of California State law that a rule or policy "of general application" must be adopted as a regulation in accordance with the State Administrative Procedures Act (APA). See Government Code §11342 and State Water Resources Control Board et al v. Office of Administrative Law 16 Cal. Rptr.2d 25 (1993). No state agency may enforce any "guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule" unless it has been adopted as a regulation. See Government Code §11347.5. The State APA in turn requires that all regulations be published in the CCR. See Government Code §11344. We would appreciate your comments on this understanding of State law. See also 40 CFR Section 300.400(g)(4) and State of Ohio v. U.S. EPA, et al. 1993 WL 264478 (D.C. Cir., July 20, 1993) for relevant Federal requirements and case law relating to the "promulgation" issue.

4. We would also call your attention to the discussion of "TBCs" in the NCP at 40 CFR Section 300.400(g)(3) and the NCP preamble at 55 Fed. Reg. 8744-8745, March 8, 1990. The discretionary status of TBCs is summarized by U.S. EPA on page 8745 of the preamble in the following paragraph:

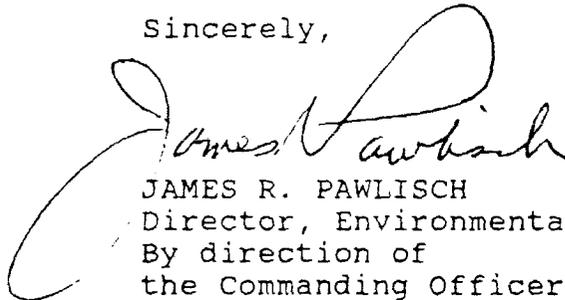
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"EPA recognizes, as the commenters point out, that, unlike ARARs, the identification and communication of TBCs should not be mandatory. EPA has revised the NCP references to TBCs to make it clear that they are to be used on an "as appropriate" basis. EPA believes that TBCs are meant to complement the use of ARARs by EPA, states, and PRPs, not to be in competition with ARARs."

We immensely value your input in the matters discussed above. As mentioned previously, our teamwork will help us enhance our understanding of the importance of State cancer potency factors and their application to the site mitigation work at MCB Camp Pendleton. We would like to emphasize again our purpose in this letter is to remove barriers to continuous improvement of the risk assessment process through quality to satisfy and please our customer, the public.

If you have any questions concerning technical aspects of this letter, please contact Jan Corbett at (619) 532-1446. Legal questions should be directed to Rex Callaway, Esq. at (619) 532-1662. Again, thank you for your cooperation.

Sincerely,



JAMES R. PAWLISCH
Director, Environmental Division
By direction of
the Commanding Officer

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