

0521



DEPARTMENT OF THE NAVY

NAVY ENVIRONMENTAL HEALTH CENTER  
2510 WALMER AVENUE  
NORFOLK, VIRGINIA 23513-2617

6200.4  
Ser EP/ 11022  
~~20 JAN 1998~~

Ms. Felicita Aquino  
Division of Health Studies  
Agency for Toxic Substances  
and Disease Registry (ATSDR)  
Mailstop E-31  
1600 Clifton Road  
Atlanta, GA 30333

Dear Ms. Aquino:

Thank you for forwarding a copy of the ATSDR Draft Final Report, "Volatile Organic Compounds in Drinking Water and Adverse Pregnancy Outcomes, United States Marine Corps Base Camp Lejeune, North Carolina," dated December 1997. Enclosure (1) provides our comments and recommendations.

If you have any questions about our comments, or would like any additional information, please contact Ms. Andrea Lunsford, Deputy Director, Environmental Programs Directorate, at (804) 363-5554, or e-mail address: [aelunsford@med.navy.mil](mailto:aelunsford@med.navy.mil).

Sincerely,

G. D. KRAMER  
Captain, Medical Service Corps  
United States Navy  
Director for Environmental Programs

Enclosure 1. Comments on "Volatile Organic Compounds in Drinking Water and Adverse Pregnancy Outcomes"

Copy to:  
ATSDR (OFF, CDR Hughart)  
USACHPPM (Dr. Buchi, DOD Lead Agent)

CLW

0000002942

Blind copy to:  
CNO (N-453)  
BUMED (MED-24)  
NAVFACHQ (Environment, W. Stafford)  
CMC (LFL)  
MCB Camp Lejeune (Mr. Neal Paul)

CLW

0000002943

COMMENTS ON DRAFT "VOLATILE ORGANIC COMPOUNDS IN DRINKING WATER AND ADVERSE PREGNANCY OUTCOMES, FINAL REPORT, UNITED STATES MARINE CORPS BASE CAMP LEJEUNE, NORTH CAROLINA"

General Comments:

1. Disclosure and Acknowledgement.

Comment: This health study was conducted during 1995 and 1996 with the collaboration and support of the Department of the Navy, and with Department of Defense Environmental Restoration Account funding provided by the Department of the Navy. This information should be stated early in the report.

Comment: A number of dedicated Navy and Marine Corps engineering and medical personnel assisted ATSDR in developing this health study. They arranged and accompanied ATSDR on site visits, provided records of environmental investigations and medical records, and provided other historical and background information. It would be appropriate for ATSDR to acknowledge the support provided by these personnel.

Recommendation: Add a paragraph at the end of the Abstract section to provide information about funding. The same paragraph could be used to acknowledge, and perhaps express appreciation for the assistance provided by Navy and Marine Corps personnel.

2. Clarity of Statements.

Comment: There are several statements in the report that include phraseology that we believe will be misinterpreted by many readers. Although the statements may seem unambiguous to epidemiologists, and would be appropriate for a professional journal, they can lead to misinterpretations/misperceptions by the public. In particular, the Abstract contains verbiage and professional jargon that would be more appropriate for a scientific journal than a communication to the public. Statements of particular concern to us are:

a. Abstract, 2<sup>nd</sup> sentence: "In 1995, data collection was begun for a retrospective cohort study of exposure to VOCs in drinking water and a variety of adverse pregnancy outcomes at the U.S. Marine Corps Base, Camp Lejeune."

Since adverse pregnancy outcomes are of much greater concern to the public than cohort studies, and the average lay person does not understand what a cohort study is, we believe the average reader will perceive that the study was initiated because there were a variety of adverse pregnancy outcomes at the base. Conversely, the message that should be communicated first in the report is that the starting point for this study was detection of contamination, and the study was undertaken to determine whether or not there was any increased incidence of commonly occurring adverse pregnancy outcomes at the base and, in the event that there were increases, to investigate if there were any associations with exposure.

CLW

0000002944 Enclosure (1)

confidence interval. It also increases the probability that the observed associations are actually due to chance.

Recommendation: Include this information in the discussion area of the results section. Discuss the impact on the significance of the findings if 95% confidence intervals had been used.

## 2. Exposure Assumptions.

Comment: The lack of data on water usage (showering and drinking) by pregnant women in each exposed house, when combined with the great variability in VOC levels due to changing patterns of well usage introduces a great risk of exposure misclassification.

Recommendation: Include this information in the discussion area of the results section.

## 3. Confounding Variables.

Comments: Previous studies have identified a large number of variables which are related to lower birth weight and which were not included in this study. These confounding variables (and some observed effects), include having prior SGA infants (297g reduction in mean birth weight); maternal height, maternal weight, low maternal weight gain (206-265g reduction); maternal diet, maternal smoking (232g reduction), maternal alcohol use (300g reduction), gestational diabetes (107g reduction); and maternal non-insulin dependent diabetes mellitus (195-345g reduction). Chlamydia infection during pregnancy has been associated with a 348g reduction in mean birth weight. In addition, SGA infants are more likely to have a SGA mother (OR=2.5) or SGA father (OR=1.7). We note that many of these effects, for example the 300g reduction in birth weight for alcohol use, are greater than the effects found in this study.

The large number of these possible confounders and their observed effects relative to the magnitude of effects found in this study suggest that the Camp Lejeune results may be strongly confounded in the magnitude of the observed effects and possibly also in the direction. It is impossible to draw any conclusions about the possible effects of in-utero TCE and PCE exposure unless data on these confounders is available. Since these data are not available, for the population studied at Camp Lejeune, the results must be interpreted with great caution.

The combination of known exposure misclassification, the potential for confounding factors of greater magnitude than the study findings, and the limitation of significant findings to extremely small population subgroups all suggest that all the reported results must be interpreted with great caution.

Recommendation: Include the above statements and information in the discussion area of the results section .

CLW

0000002945

4. In-Utero Exposure.

Comment: While it may be valuable to further study the possible effects of in-utero exposure to TCE and PCE, it would be difficult and probably unrewarding to conduct additional studies on this population due to the very low statistical power that such studies would have, their high cost, and the lack of data on individual exposure. In addition, the passage of time (12 to 29 years) since the exposures occurred would make it extremely difficult to locate and contact the study population (mother and children) and would introduce a very high risk of recall bias regarding confounding variables and water usage.

Recommendation: Include this information in the Conclusions section of the report.

CLW

0000002946