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FYI



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Document Control Officer (TS-790)  
Attention: FYI Coordinator  
Office of Toxic Substances  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, DC 20460

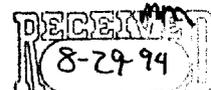
Subject: TSCA FYI Submission on Arsenic Epidemiology Data

Dear Sir/Madam:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act, the Atlantic Richfield Company (ARCO) is submitting a FYI notice on preliminary data on epidemiological data concerning exposure to arsenic in drinking water. This study was designed as a preliminary feasibility study and not as a definitive epidemiological study. ARCO does not manufacture, process or distribute arsenic in commerce.

ARCO retained the services of Gradient Corporation to examine the statistical correlation between the level of arsenic in drinking water and the occurrence of kidney or bladder cancer in U.S. populations. According to the study protocol, concentrations of arsenic in municipal water supplies and cancer data were to be collected by Gradient Corporation for the three locations identified in a 1984 study focusing on arsenic and skin cancer, by Andelman and Barnett (Millard County, UT; Lassen County, CA; and Lane County, OR), and possibly other locations identified from the STORET and Federal Reporting Data System (FRDS) databases, including a selected area in Alaska (Kreiss et al., 1983). The combined population of the three identified counties was almost a quarter of a million people.

ARCO recently received a tabulation (attached) of the arsenic and cancer occurrence data from geographic areas identified from the FRDS database, representing about 5% of the population specified in the protocol (see attachments), and an unknown fraction of the total number of U.S. residents exposed to elevated levels of arsenic in their drinking water. These are preliminary data whose significance cannot be determined without additional study. While the summary mortality and incidence



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data suggest that the rates of kidney and bladder cancer in the "exposed" areas are several times those in the "control" areas, we believe that serious limitations in the data prevent an inference of increased risk of bladder or kidney cancer due to ingested arsenic. We do not have the information necessary to evaluate these limitations and therefore believe that the data are not currently interpretable. The most serious limitations include:

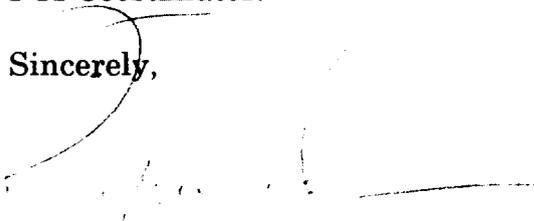
**Sample size and sampling bias:** The included "exposed" populations represent a small fraction of the total U.S. population exposed to elevated levels of arsenic in their drinking water. The small sample size and the lack of detail regarding sampling strategy precludes the assumption that the sample data are representative of the population from which they were drawn. Also the small number of cases identified may limit the ability to adequately control for confounding.

**Confounding:** The occurrence of both kidney and bladder cancer varies by sex, age, geographic area, and time period, as well as other factors, including various exposures in addition to arsenic. Stratification by time period, sex, and geographic region was collapsed, precluding control for differences in occurrence rates related to these factors.

**Immigration/emigration and the ecological fallacy:** It cannot be determined from the data whether the affected individuals were exposed to the municipal water supply, and if so, whether their exposure occurred before their disease or occurred over a sufficiently long period to have had an effect on the development of their disease.

When we receive additional reports on this study, we will send them to the FYI Coordinator.

Sincerely,



Robert J. Trunek

RJT/RNR/isc

Table 1: RAW MORTALITY DATA: (Abstracted from Database)

July 5, 1994

Parameter	Cancer Type	Age_group Category	≤ 10 µg/L "Control"	> 10 µg/L "Exposed"
avg. As in H <sub>2</sub> O, µg/L	Bladder	Age_group_1	2	41
avg. As in H <sub>2</sub> O, µg/L	Bladder	Age_group_2	2	43
avg. As in H <sub>2</sub> O, µg/L	Bladder	Age_group_3	2	64
avg. As in H <sub>2</sub> O, µg/L	Kidney	Age_group_1	2	51
avg. As in H <sub>2</sub> O, µg/L	Kidney	Age_group_2	2	45
avg. As in H <sub>2</sub> O, µg/L	Kidney	Age_group_3	2	52
(yrs.) Number of Deaths	Bladder	Age_group_1	(8.2) 22	(10.9) 2
(yrs.) Number of Deaths	Bladder	Age_group_2	(8.2) 447	(10.9) 6
(yrs.) Number of Deaths	Bladder	Age_group_3	(8.1) 2,267	(10.8) 12
(yrs.) Number of Deaths	Kidney	Age_group_1	(8.2) 127	(10.9) 5
(yrs.) Number of Deaths	Kidney	Age_group_2	(8.2) 771	(10.9) 5
(yrs.) Number of Deaths	Kidney	Age_group_3	(8.1) 1,593	(10.8) 14
Population	Bladder	Age_group_1	3,004,053	7,401
Population	Bladder	Age_group_2	1,069,042	2,505
Population	Bladder	Age_group_3	1,062,408	2,418
Population	Kidney	Age_group_1	3,004,053	7,401
Population	Kidney	Age_group_2	1,069,042	2,505
Population	Kidney	Age_group_3	1,062,408	2,418

Table 2: SUMMARY MORTALITY DATA: (Annual mortality rate per 100,000 population)

Age Group	Exposure Status	Kidney Cancers	Bladder Cancers
Age Group #1 (25-49)	Control	0.5	0.1
	Exposed	6.5	2.6
Age Group #2 (50-64)	Control	8.8	5.1
	Exposed	18.2	21.9
Age Group #3 ( 65 + )	Control	18.6	26.4
	Exposed	53.6	45.9
OVERALL All ages (> 24 yrs)	Control	5.9	6.5
	Exposed	18.4	15.3

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Table 3: RAW INCIDENCE DATA (Calif.): (Abstracted from Database)

Parameter	Cancer Type	Age Category	≤ 10 µg/L "Control" Fresno, CA	> 10 µg/L "Exposed" Hanford, CA
avg. As in H <sub>2</sub> O, µg/L	Bladder	All ages (> 24 yrs)	2	58
avg. As in H <sub>2</sub> O, µg/L	Kidney	All ages (> 24 yrs)	2	58
(yrs.) Number of Cases	Bladder	All ages (> 24 yrs)	(5.5) 338	(5.5) 34
(yrs.) Number of Cases	Kidney	All ages (> 24 yrs)	(5.5) 181	(5.5) 19
Population	Bladder	All ages (> 24 yrs)	487,344	21,840
Population	Kidney	All ages (> 24 yrs)	487,344	21,840

Table 4: SUMMARY INCIDENCE DATA (Calif.): (Incidence rate per 100,000 per year)

Age Group	Exposure Status	Kidney Cancers	Bladder Cancers
OVERALL	Control	6.8	12.6
All ages (> 24 yrs)	Exposed	15.8	28.3

Table 5: National Cancer Institute SEER Data: (1986-90 rates per 100,000 per year)\*\*

Age Group	Parameter	Kidney Cancers	Bladder Cancers
All ages, age adj. to 1970 U.S. pop.	Incidence	8.5	16.9
	Mortality	3.4	3.3
EST. OVERALL	Incidence	13.3	26.4
All ages (> 24 yrs)	Mortality	5.3	5.2

\*\* Miller BA, Ries LAG, Hankey BF, Kosary CL, Hurray A, Devesa SS, Edwards BK (eds). "SEER Cancer Statistics Review, 1973-1990", National Cancer Institute, NIH Publication No. 93-2789, Bethesda, MD, 1993. pp. XI-6, XI-7, XXVI-6, XXVI-7.