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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

AUG 11 1992

Mr. Robert F. Jones
Director, Environmental Division
Naval Submarine Base New London
Code 803 Box 400
Groton, Connecticut 06349-5000

Dear Mr. Jones:

In response to your July 16, 1992, letter, the Agency for Toxic Substances and Disease Registry (ATSDR) has prepared a health consultation that discusses the potential for adverse health effects of boron in drinking water. It is our belief that a written document outlining the basis for our health-based opinion (that boron in the private wells did not represent a health hazard) would facilitate discussions with the public and would provide the public with information that would help them understand the basis for the Environmental Protection Agency's (EPA's) draft Lifetime Health Advisory.

A public meeting is scheduled for 7:00 p.m. Tuesday, August 18, 1992, at the Shepherd of the Sea Chapel, Fellowship Hall, where ATSDR will present to the public the information in the health consultation. Navy personnel are invited to attend the public meeting.

ATSDR will send the health consultation to the U.S. Environmental Protection Agency, State of Connecticut Department of Health Services, and State of Connecticut Department of Environmental Protection with a cover letter inviting them to attend the public meeting. Additionally, ATSDR will mail the health consultation and an ATSDR FACT SHEET on Wednesday, August 13, 1992, to each of the 27 residents whose private wells were sampled.

In the health consultation, ATSDR made recommendations for additional sampling. We invite the Navy to discuss your response and proposed actions to the recommendations in the health consultation with us.

If you have any questions or comments, please feel free to call, write, or fax Ms. Carole Diamond, Federal Programs Branch at:

ATSDR
Division of Health Assessment and Consultation
1600 Clifton Road NE (E-56)
Atlanta, Georgia 30333
404-639-6068
FAX 404-639-6076

Sincerely yours,

Robert C. Williams, P.E.
Director
Division of Health Assessment
and Consultation

Enclosure

cc:
LCDR Ruth S. Noonan
Mr. Bill Mansfield

Health Consultation

Boron in Private Drinking Water Wells Neighboring
U.S. Naval Submarine Base, New London (10G6)
Groton, New London County, Connecticut
August 10, 1992

Background and Statement of Issues

The Agency for Toxic Substances and Disease Registry (ATSDR) was requested by the Department of the Navy, Naval Submarine Base, New London, to attend and participate in a public meeting to discuss the health effects of boron in drinking water [1]. Sampling and analysis of selected off-base drinking water wells in the neighboring homes detected levels of boron up to 2 parts per million (ppm) which can also be expressed as 2 milligrams per liter (mg/L) [1,2]. For this consultation, concentrations of boron in water will be expressed in mg/L to assist in understanding the dose calculations presented later.

Because the reported levels of boron exceed a draft Environmental Protection Agency (EPA) Lifetime Health Advisory (LHA) level of 0.6 mg/L, nearby residents who use private well water for drinking and other household uses have expressed concerns. Copies of ATSDR's Public Health Statement (Chapter 1 of the Toxicological Profile for Boron) were distributed by the Navy to those citizens whose private wells were tested [3]. ATSDR has previously stated that the levels detected in the wells were much lower than levels found to be dangerous to humans [4].

The purpose of this consultation is to provide some background information that was used as the basis for that opinion. The consultation will focus only on issues related to health effects that might be expected from exposures to boron in drinking water at the levels detected. A glossary of terms, a listing of various guidelines related to boron, and basic formulas used to derive the guidelines are provided in Attachments.

ATSDR is currently completing a more comprehensive public health assessment that will address many other community concerns. The public health assessment is expected to be available for public comment by mid-September of 1992.

General Discussion of Boron Toxicity

Boron is widely used in pharmaceuticals, cosmetics, foods, agricultural products, and in a variety of industries [3,6]. Because of its wide use and natural occurrence, it is estimated that humans (probably adults) ingest as much as 10 - 25 mg of boron per day through their water and foods [3]. Boron levels in

drinking water are not routinely reported. However, a limited survey of public water supplies indicated levels of boron ranging from less than 0.005 mg/L to greater than 2 mg/L, with concentrations up to 0.4 mg/L in 90% of the systems [3].

Boron is taken up in small quantities by fruits and vegetables. The resulting boron levels depend in part on the naturally occurring levels of boron in the water and soil. Additional levels of boron may be added to the human diet as a result of the use of boron (as boric acid and sodium borate) as fungistatic agents on vegetables, fruits, and trees [3,6]. The Food and Drug Administration (FDA) has established a tolerance level of 8 ppm boron (total) for citrus fruits covering residues from postharvest applications and naturally occurring boron [7]. The FDA also permits up to 350 ppm of total boron in modified hop extracts used in the production of beer [8] and regulates the use of boron (as boric acid and sodium borate) in paperboard, textile, and other products that may come in contact with food [7]. Use of boron (as sodium borate) as a direct food additive is prohibited (as cited in Reference 6).

Cosmetic, clinical, and consumer products containing boron (usually as sodium borate or boric acid) also contribute to human intake of boron. These products come in contact with all body surfaces, including the skin and the mucous membranes of the mouth, vagina, and eyes [3,6].

The residents whose wells contain boron are primarily concerned about adverse health effects that might be expected to occur from long-term ingestion of water containing boron up to 2 mg/L. The remainder of this discussion will focus on that issue. Although there are currently no regulatory standards for levels of boron in water, there are a number of EPA and ATSDR guidelines. (See Attachments I and II). These guidelines are expressed both as concentrations of boron in water (mg/L) and as daily doses of boron (mg per kilogram of body weight per day: mg/kg/day) that are not expected to cause adverse noncancerous health effects. All of the guidelines are based on available toxicological information (dose levels that have produced or have failed to produce toxic effects in humans and animals) and a number of exposure assumptions as discussed below.

The guideline concentrations (mg/L) and doses (mg/kg/day) were developed using uncertainty factors (UFs), which are intended to reduce the risk of adverse health effects. For example, UFs are typically applied to account for:

- unknowns related to extrapolating animal data to humans,

- possible differences in human reactions to the substance, and
- the use of a Lowest Observed Adverse Effect Level (LOAEL) because a defined, "true" No Observed Adverse Effect Level (NOAEL) is not available.

Each UF is assigned a value, typically 10, and the UFs are then multiplied together. The resulting product (total UF -- typically ranging from 10 to 1,000) is then divided into the most sensitive LOAEL value (or a reliable NOAEL if one exists) to determine a dose (mg/kg/day) protective of public health and a calculated concentration in water.

When making decisions about acceptable doses and levels of contaminants in water, human data are preferred. However, in the case of boron, no peer-reviewed studies were located that directly examined the long-term health effects in humans who chronically (more than a year) consumed low levels of boron in either food or water. Human data are available for short-term exposures (one to three days) to high levels of boron (184-505 mg boron/kg/day) because of accidental or suicidal ingestion of boric acid [3].

In one incident, 11 infants (one or two days old) were inadvertently given formula contaminated with boric acid for one to three days [3]. It was estimated that the individual infants ingested total amounts of boron ranging from 2,000-14,000 mg over the one to three day period. Signs and symptoms of toxicity included gastrointestinal disturbances (persistent vomiting, diarrhea, and colicky abdominal pain), rashes and sloughing of the skin, and neurological changes (tremors, weakness, convulsions), and indications of liver toxicity. Five of the 11 infants died.

Among the infants who died, estimates for total boron ingested ranged from 4,500-14,500 mg. Estimated total boron ingested among surviving infants ranged from 2,000-4,500 mg. Estimated doses to produce the gastrointestinal effects were 184 mg boron/kg/day and greater. Boron doses estimated to be 505 mg boron/kg/day or greater in the infants were associated with more severe effects including death [3].

In an incident involving adults, two women attempted suicide by consuming boric acid-containing substances at estimated doses of about 240 to 895 mg boron/kg. Vomiting was the only sign of toxicity. Both women recovered completely after about 96 hours [3].

Because of the lack of human data, health officials depend upon data from animal studies for information on the long-term toxicity of boron, including its potential to cause cancer. Acute toxicity studies (less than 14 days) in animals indicate that doses of 500 mg boron/kg/day or greater will result in toxic responses similar to those observed in humans at these high levels [3]. In these studies, as in most toxicological studies, boron was in the form of boric acid or sodium borate.

In this case, since residents are drinking low doses of boron over an extended time period, it is more relevant to look at the results of studies addressing intermediate (more than 14 days) and chronic exposures (more than a year). Such studies have been conducted in several different species (mice, dogs, and rats) using either feed or water contaminated with known amounts of boron [3]. Results of these studies indicate that:

- Boron was not carcinogenic in either mice or rats at daily doses estimated at 96 mg and 117 mg boron/kg/day, respectively.
- Reproductive effects, particularly testicular effects, appear to be the most sensitive indicator of toxicity.
- The reproductive effects have occurred at doses above 20 mg boron/kg/day, but are more likely to be seen in increasing frequencies at doses above 40 mg boron/kg/day.
- Rats and dogs appear to be more sensitive to the testicular effects than mice.
- For many of the toxicologic endpoints measured, including testicular effects, doses below 20 mg/kg/day have not been associated with toxicity. The data indicate that a clear dose response relationship is evident; that is, the greater the dose, the greater the effect.

Toxicologists routinely select one study, which they believe shows the most reliable LOAEL or NOAEL, to use in calculating a more conservative dose level to be more certain of protecting public health. For boron, EPA toxicologists selected a two-year study conducted with dogs exposed to boron-dosed feed [9]. Boron doses ranged from approximately 1.5 mg boron/kg/day to 9 mg boron/kg/day. No adverse testicular or other effects were observed in the dogs treated for two years at doses up to 9 mg/kg/day [9]. EPA toxicologists also reviewed a subchronic study in which dogs were exposed to approximately 29 mg boron/kg/day in their feed for 38 weeks [9]. Severe testicular and other effects were noted in these dogs as early as 26 weeks

into the study. The 9 mg boron/kg/day dose was chosen as the NOAEL for boron [9].

The NOAEL of 9 mg boron/kg/day can be used to calculate the concentration in water that humans must drink in order to obtain that dose. The standard assumptions are that a 70 kg adult (approximately 150 pounds) will drink two liters (L), which is slightly more than two quarts, of the contaminated water (2 mg boron/L) every day over a lifetime. Therefore, a water concentration of 320 mg/L is calculated to represent a level that would not be expected, based on the results of an animal study, to cause adverse health effects in humans. However, because scientists are not confident that animals and humans are equally sensitive to toxic agents, the 320 mg boron/L water concentration was divided by 10 (an UF previously discussed) to take into account the uncertainties associated with extrapolating animal data to humans. The resulting concentration is lowered to 32 mg/L.

Not all humans react the same way to nutrients, drugs, and hazardous substances. Because of uncertainty about differences in human reactions, the 32 mg/L water concentration was further divided by an UF of 10. The resulting boron concentration of 3.2 mg/L (rounded down to 3 mg/L) represents EPA's Drinking Water Equivalent Level (DWEL) which is a lifetime (70 yrs) exposure level for drinking water (assuming that all exposure is from that medium) at which adverse noncancerous health effects would not be expected.

Drinking water is not the only source of boron intake, and EPA further assumed that only 20% of human intake of boron is from water. EPA then divided the DWEL by 5 (20%) to obtain a Lifetime Health Advisory (LHA) level of 0.6 mg/L. In terms of dose (mg/kg/day), using the standard assumptions, drinking water containing 0.6 mg/L would result in a boron dose in adults of 0.017 mg/kg/day.

Summary of Calculation Procedures

NOAEL from two-year dog study using dosed-feed = 9 mg/kg/day

UF = 100 (10 for extrapolating animal data to humans and 10 for differences in human sensitivities)

RfD = $\frac{\text{NOAEL}}{\text{UF (total)}} = \frac{9 \text{ mg/kg/day}}{100} = 0.09 \text{ mg/kg/day}$

DWEL = $\frac{\text{RfD x body weight (kg)}}{\text{Daily Water Ingested (L)}} = \frac{0.09 \times 70}{2 \text{ L}} = 3.15 \text{ mg/L}$

LHA = DWEL x 20% = 3 mg/L x 20% = 0.6 mg/L

Site Specific Discussion

The highest boron concentration reported in wells near the base was 2 mg/L. Assuming residents in the area of the submarine base area drink 2 L of water containing 2 mg boron/L every day over a lifetime, adults would ingest 4 mg boron per day which would result in an approximate dose of 0.06 mg/kg/day. Children weighing 10 to 16 kg, drinking 1 L per day would obtain doses ranging from 0.125 to 0.2 mg/kg/day, respectively. These calculated doses for children and adults are more than 100 times lower than doses that produced adverse health effects in long-term animal studies and more than a 1,000 times lower than those reported from short-term exposures of humans, particularly infants, who accidently ingested boric acid.

It is important to note that the assumptions concerning daily intake of boron-contaminated water ingested (1 L for children and 2 L for adults) do not take into account daily fluid intake that comes from other sources while at work or school, where many people spend a good portion of their days. The estimates also do not consider the percentages of fluid intake from beverages not prepared with the local water (e.g., soda, milk, juice). The assumptions of lifetime exposures do not take into account changes in locations and residences. All these factors reduce the total daily intake of contaminated water. Finally, the estimates assume that a maximum of 2 mg boron/L will be ingested daily over a lifetime. The limited sampling data available for the residential wells indicate that concentrations of boron less than 2 mg/L are common, although the data are insufficient to state with confidence if the observed concentrations will remain constant or change with the seasons.

Conclusions

Based on the information available, ATSDR concludes that:

1. Maximum levels of boron detected in water from residential wells near the Naval Submarine Base New London do not pose a health threat to adults or children.

2. Data are insufficient to determine the source of the boron in the water, or if the levels detected represent maximum levels that have occurred in the past or may occur in the future. Additionally, current levels in groundwater from unsampled wells are unknown.

Recommendations

1. Determine background levels for boron in area groundwater.

2. Continue to monitor residential wells until it has been determined that the levels of boron do not increase over time. Quarterly monitoring of wells for one year is suggested. Hydrogeological data should be used as the basis for selection of the wells to be monitored.

3. If either the actual levels of boron or average levels of boron in water exceed the DWEL for more than two monitoring periods, ATSDR will evaluate that information.

We hope the information provided above and in the Attachments helps in understanding the public health implications of boron in drinking water. If we can be of additional assistance, please contact Carole Diamond at (404) 639-6070 or Lydia Ogden Askew at (404) 330-9543 (24 hours).

Consultation Prepared by:

Allan S. Susten

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Chief, Technical Support Section
Emergency Response and Consultation Branch

Concurrences:

Darcy L Shaner — 8/10/92
Chief, Federal Programs Branch — Date

C. Hennett — 8/10/92
Chief, Emergency Response Branch — Date

8/10/92
Director, Division of Health Assessment and Consultation — Date

Attachments

References

1. Letter from Robert F. Jones (Department of Navy, Naval Submarine Base New London) to Dr. Allan S. Susten (ATSDR) requesting participation in Public Meeting, July 16, 1992.

2. Summary of Residential Well Data (First, Second, and Third Rounds), from (Draft) Installation Restoration Study, Naval Submarine Base-New London, Groton CT, August 1991.

3. Example of letter and attachments from Nelson Goddard (Department of Navy) to citizens informing the citizens about the status of their wells, June 1992.

4. Newspaper article entitled, "Agency Says Boron Levels In Wells Near Base Are No Threat," *The Day,* Friday July 17, 1992.

5. Beyer KH, Bergeld WF, Berndt WO, et al., Final Report on the Safety Assessment of Sodium Borate and Boric Acid. J Am Coll Toxicol 2:87-125, 1983.

6. Toxicological Profile for Boron (Draft for Public Comment), October 1990.

7. Federal Register 34 (181) 14651, September 1969.

8. 21 CFR 172.520, p56, April 1991.

9. Weir RJ and Fisher RS. Toxicologic Studies on Borax and Boric Acid. Toxicol Appl Pharmacol 23:351-364, 1972.

Attachment I

Glossary

Acute Exposure -- Exposure to a substance for a duration of 14 days or less, as specified in ATSDR's Toxicological Profiles.

Carcinogen -- A substance capable of inducing cancer.

Chronic Exposure -- Exposure to a chemical for 365 days or more, as specified in ATSDR's Toxicological Profiles.

Drinking Water Equivalent Level (DWEL) -- A lifetime (70 yrs) exposure level specific for drinking water (assuming that all exposure is from that medium) at which adverse, noncarcinogenic health effects would not be expected to occur.

Intermediate Exposure -- Exposure to a substance for a duration of 15-364 days, as specified in ATSDR's Toxicological Profiles.

Kilogram (kg) -- a unit of mass. One kilogram is equal to 2.2 pounds.

Milligram (mg) -- a unit of mass. One milligram is equal to one thousandth of a gram (one millionth of a kilogram).

Lifetime Health Advisory (LHA) -- An acceptable level in drinking water that is 20% of the DWEL. A health advisory is not a legally enforceable standard but serves as technical guidance to assist federal, state, and local officials.

Liter (L) - a unit of volume. For liquids, 1 liter is 4% more than a quart.

Lowest-Observed-Adverse-Effect-Level (LOAEL) -- The lowest dose of chemical in a study or group of studies that produces statistically or biologically significant increases in frequency or severity of adverse effects in the exposed population as compared to appropriate controls.

Minimal Risk Level (MRL) -- A route specific estimate of daily human exposure to a substance that is likely to be without an appreciable risk of deleterious effects (noncancerous) over a specified duration of exposure.

No-Observed-Adverse-Effect-Level (NOAEL) -- The dose of chemicals in a study or group of studies at which there were no statistically or biologically significant increases in frequency or severity of adverse effects in exposed populations as compared to appropriate

controls. Effects may be produced at this dose, but are not considered adverse.

Reference Dose (RfD) -- An estimate (with uncertainty spanning at least an order of magnitude) of the daily exposure of human populations to a substance that is likely to be without risk of deleterious effects during a lifetime.

Subchronic Exposure -- See Intermediate Exposure.

Uncertainty Factors (UFs) -- Factors used to account for (1) variation in sensitivity among the members of a human population, (2) the uncertainty in extrapolating animal data to human populations, (3) the uncertainty in extrapolating from data obtained in a study that is less than a lifetime exposure, and (4) the uncertainty in using LOAEL data rather than NOAEL data. Usually each of these factors is set equal to 10. The total product of uncertainty factors is used to acceptable doses.

Attachment II

BORON GUIDELINES
For Drinking Water

EPA

Health Advisories

For a 10 kg Child

- one-day - 4 mg/L
- ten-day - 0.9 mg/L
- longer-term - 0.9 mg/L

For a 70 kg Adult

- longer-term - 3 mg/L
- DWEL - 3 mg/L
- Lifetime - 0.6 mg/L
- RfD - 0.09 mg/kg/day

ATSDR

Minimal Risk Levels (MRLs)

- Intermediate oral MRL (draft) - 0.09 mg/kg/day