



On March 19, 2003, the U.S. Environmental Protection Agency (EPA), the Pennsylvania Department of Environmental Protection (PADEP), and American Household, Inc.. met with the public to inform them of the discovery that low levels of 1,4-dioxane were present in the treated water being distributed to customers of the Bally municipal water supply. Although the levels were low and did not present an immediate health threat, EPA was concerned about long-term exposure. EPA, PADEP, and American Household, Inc., committed to evaluate the Bally water treatment system and determine what options can be used to remove 1,4-dioxane from the Borough water supply. EPA and American Household, Inc., have prepared this update to report the progress of the on-going water treatment system review.

Interim Water Supply

While EPA and American Household, Inc., complete their evaluation of the options available to address low levels of 1,4-dioxane in the water supply, American Household, Inc., is providing bottled water, free of charge, to all residents and businesses who request it and who are customers of the Bally Borough Water System. If you wish to order delivery of bottled drinking water, contact Deer Park at 800-950-9907. Be sure that Deer Park knows you are a Bally Borough Water System customer. You will be asked to enter into a service agreement, but the costs will be paid by American Household, Inc.

Progress of Options Evaluation

Two options are being evaluated to address the current 1,4-dioxane concerns. As discussed at the public meetings, installing a new well is an option. Another option is treating 1,4-dioxane at the currently operating Bally Borough supply well.

Option 1: Install a New Well – Arcadis G&M, Inc., a consultant to American Household, Inc., has completed geologic evaluations and land use and ground water impact evaluations. Based on the information gathered, several potential well sites have been selected for more detailed testing and drilling. The next step is to review potential well sites with private property owners and the PADEP.

Option 2: Treat 1,4-Dioxane at the Borough Supply Well – Successful treatment of 1,4-dioxane involves a carefully balanced oxidation process using ultraviolet light. Oxidation may be accomplished using peroxide or ozone. The first phase of oxidation testing, using peroxide, has been completed. Arcadis G&M, Inc., is now evaluating the fullscale system design. Ozonation testing is currently underway and should be completed in the near future.

<u>Please note</u>: You can't treat your own water supply by adding peroxide or ozone to it.

Outstanding Issues of Note

The PADEP is responsible for an environmental program called NPDES, the National Pollutant Discharge Elimination System. Under the NPDES program, it is PADEP's responsibility to establish a concentration of 1,4-dioxane that is acceptable for discharge to surface water bodies, such as streams, in Pennsylvania. PADEP is currently working to establish an acceptable level. Depending on the level established, water from Bally Borough Well No. 3 may require treatment before the water can be discharged. This could have a significant impact on the evaluation of available water supply options.

Next Update:

Expect another update June/July 2003.

For More Information

For additional information about the Bally Borough Water Supply System evaluation, please contact:

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Or visit our website: www.epa.gov/superfund

Addendum:

Responses to Questions Raised at March 2003 Public Meetings

The following questions were raised at the public meetings held on March 19, 2003. The answers are being provided with this update because these questions required research and could not be answered "on the spot."

1. What types of cancer have been

associated with 1,4-dioxane? There are very few human studies available. However, various sources show a likely association between 1,4dioxane exposure and liver, lung, and nasal tumors in rats and mice. Gallbladder cancer in guinea pigs is also listed in EPA's risk information database. Scientists believe these cancers are related to 1,4-dioxane because they occurred in a significant number of the test animals that were exposed to the compound. Some studies have found single instances of different kinds of cancers, such as kidney cancer or leukemia, in test populations. Those cancer types were not believed to be associated with 1,4-dioxane because they did not occur consistently among the test animals or did not occur in significantly greater numbers among the test animals than in the untreated control animal population. These cancers probably arose from other causes that were independent of the studies.

In the few available studies of workers exposed to 1,4-dioxane, researchers have failed to find a significant increase in cancer deaths among workers. The cancers found in those studies were single instances of different types of cancer, and therefore probably arose from other causes.

2. Isn't 1,4-dioxane regulated as an "inert" ingredient in pesticides? What does "inert" mean in this context? Under the law that

regulates pesticides (the Federal Insecticide, Fungicide, and Rodenticide Act), an "inert" ingredient is simply any intentionally added ingredient in a pest product which is not added as a killing or controlling agent. In 1997, EPA issued guidance encouraging the use of the term "other ingredients" instead of inert, because it was apparent that many consumers believed "inert" meant "harmless." As noted on EPA's website, "Since neither the federal law nor the regulations define the term 'inert' on the basis of toxicity, hazard or risk . . . it should not be assumed that all inert ingredients are nontoxic."

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In fact, when EPA divided "inert" ingredients into four categories (inerts of toxicological concern, potentially toxic inerts, inerts of unknown toxicity, and inerts of minimal concern), 1,4-dioxane was placed in the first category -- inerts of toxicological concern. EPA therefore encourages the substitution of other ingredients for chemicals like 1,4dioxane, and issued new labeling requirements for these chemicals.

3. What effects might 1,4-dioxane have on pets, specifically: Dogs, 7-8 lbs.? Hamsters? The daily dose that a dog of this size would be expected to get from the drinking water would be about 500,000 to 2,000,000 times less than a lethal dose reported in the scientific literature. The dog's total lifetime dose would be about 100 to 400 times less than the reported lethal dose. A hamster's expected daily dose would be about 200,000 times less than the lethal and toxic doses reported in the literature. The hamster's lifetime dose would be about 270 times less than the toxic and lethal doses. While no minimum toxic dose could be found in the literature, these factors provide a considerable margin of safety. (The minimum toxic dose would be the lowest dose at which negative health impacts have been documented.)

Perhaps most importantly, it should be noted that FDA recommendations allow 1,4-dioxane

to be present, as an additive, in new veterinary medicines up to 380 ppm, with a permitted daily exposure of 3.8 mg/day per animal, regardless of size or life span. The hamster's dose from the Bally water would be 2500 times less than the FDA-permitted daily exposure. The dog's dose from this water would be approximately 190 to 750 times less than the FDA-permitted daily exposure. The proportional difference between the dog's dose and the hamster's is based on the differences in the animals' sizes, life spans, and daily and lifetime water-consumption rates.

4. What is the exact analytical procedure for 1,4-dioxane? What are the quantitative confidence limits on the data? This question is likely to be of greatest interests to chemists. EPA used a modified Method 8260, which is a gas chromatography/mass spectrometry method. The following quality criteria were reported, which can give some idea of the confidence limits around the data and the kinds of quality-control checks that were used:

- All surrogate recoveries were between 98-103% recovery (acceptance limits 80-120%).
- No 1,4-dioxane was found in field, trip, or laboratory blanks.
- The matrix spike and matrix spike duplicate recoveries were 67% and 81%, with a relative percent difference (RPD) of 18. The acceptance limits were 80-120% recovery and an RPD of 15%, so these were slightly outside the acceptance limits. (However, because the surrogates were acceptable, overall this did not require the data to be considered quantitatively "estimated.")
 - A standard from a source different from that used to make the calibration curve (second source) gave a recovery of 108.6%.
- The % relative standard deviation of the initial calibration curve was 8.7% (acceptance limit 20%).
- The continuing calibration standards had % differences of 21.7% and 16.9% A R 5 U U U 1 6

within the acceptance limits of 25%.

5. What is the basis of the MCLs for TCE

and 1.1.1-TCA? MCL stands for Maximum Contaminant Level. An MCL for any substance is the highest amount of that substance that is allowed to be present in public water supplies. The MCLs for TCE and 1,1,1-TCA were developed in the 1980s, under the Safe Drinking Water Act. At the time these standards were set, the procedure was to identify a "Recommended MCL" (RMCL) for each chemical. The RMCL was based on potential health risks. When the RMCLs were identified, the final standards - the MCL - were set as close to the RMCL as was feasible. Feasibility must be the basis of regulatory standards in order for them to be attainable and enforceable.

The RMCL for TCE is zero, because TCE is categorized as a probable human carcinogen, and EPA believes that zero exposure to cancercausing substances is the ideal. However, the MCL of 5 ppb was set because that was as close to zero as a water system could demonstrably get, based on the available technology for removing TCE from water and for detecting its presence in water (practical quantitation level 5 ppb).

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The RMCL for 1,1,1-TCA was 200 ppb, and the MCL was also set at 200 ppb. This was derived from an acceptable daily intake of 1000 ppb, and an assumption that the drinking water should constitute no more than 20% of a person's daily intake of 1,1,1-TCA. The acceptable daily intake was the level expected to be without significant risk even for daily lifetime exposure. For 1,1,1-TCA, the risks that EPA was guarding against were from potential effects on the central nervous and cardiovascular systems, and the liver.

The following questions are still being researched by EPA:

1. What effects might 1,4-dioxane have on cows (and what accumulation in milk and meat might occur)?

2. What effects might 1,4-dioxane have on people consuming vegetables from gardens that used the Bally water?

For additional information about health-related concerns or these questions and answers, please contact EPA's toxicologist for the site: Jennifer Hubbard: 215-814-3328 or 1-800-553-2509; or hubbard.jennifer@epa.gov

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US EPA UPDATE: Bally Borough Water Supply System Evaluation