ARSENIC

December 5, 2005

MEMORANDUM TO: All Participants in the Public Comment Process on Arsenic

RE: Comments Received and Actions Taken

Actions Taken

The Secretariat of the Federal-Provincial-Territorial Committee on Drinking Water (Secretariat) appreciates the comments received from participants in the public comment process on the document entitled "Arsenic in Drinking Water." After due consideration of ***all*** comments received on the arsenic consultation document during the comment period, the Federal-Provincial-Territorial Committee on Drinking Water (Committee) decided at its October 2005 meeting to adopt a Maximum Acceptable Concentration (MAC) of 0.01 mg/L (10 µg/L) for arsenic in drinking water, based on municipal-scale treatment achievability. Certified residential treatment devices are available to remove arsenic to well below this concentration. Every effort should be made to maintain arsenic levels in drinking water as low as reasonably achievable (ALARA).

The arsenic supporting document was rewritten to reflect the consensus opinion of the Committee and subsequently approved by the Federal-Provincial-Territorial Committee on Health and Environment in November 2005.

Comments Received and Responses

Below is a brief summary of the ***major*** comments received (◆) by the Secretariat during the public comment period and responses to them:

Guideline

◆ The guideline should be lowered to 10 ppb since it would harmonize with the current drinking water guidelines of WHO and the U.S. EPA and with the Codex standard for natural mineral waters. In particular, consideration should be given to the EPA's decision to set the drinking water standard for arsenic higher than the technically feasible level of 3 µg/L, because the EPA believes that the costs would not justify the benefits at this level.

The establishment of a guideline takes into consideration international regulatory decisions in addition to Canadian cost and implementation considerations. The final MAC of 10 µg/L was established by the Committee after taking account of the Canadian

situation and keeping in mind that arsenic is a Group 1 carcinogen and that levels in drinking water must be maintained as low as reasonably achievable.

- Although the rationale for the difference in guidelines for municipal- and residential-scale treatment is clearly explained, one uniform guideline for all consumers would be more readily acceptable from a public perception point of view.

  Having two guidelines meets the ALARA principle. Nevertheless, after the Committee gave careful consideration to all comments, it decided to propose one guideline value, 10 µg/L, for all consumers.

  Exposure

- The 1984 Nova Scotia data referenced in the document were collected in areas containing bedrock known to have elevated arsenic levels and are therefore not representative of typical arsenic levels in groundwater across the province.

  More recent exposure data (1991–1997) from a larger data set (21 635 samples) have been added.

- Limited information is provided on arsenic levels in the major aquifer systems providing water supplies for urban populations or in the major (and minor) sources of surface freshwater supplies of drinking water. The consultation document needs to address the adequacy of existing information on arsenic in different geological and physiographic regions. It is difficult to evaluate the impact of a given MAC on the regulation and control of local supplies without the necessary background analytical information.

  Information on the occurrence of arsenic in different geological locations is very limited. Addressing this is beyond the scope of the supporting document.

- If arsenic exposure through the water supply is a source of concern, then one would expect it to be equally important to clarify the role of food preparation and processing in transforming arsenic compounds and making available for human exposure the more toxic tri- and pentavalent forms of inorganic arsenic.

  Information on exposure to arsenic via food preparation is limited. The U.S. EPA indicates that preparing foods with arsenic-containing water may increase arsenic

content by as much as 10–30% for most foods; beans and grains that absorb water when cooked may absorb up to 200–250%. This information has been added to the document.

Analytical Methods

- This section notes that atomic absorption via gaseous hydride formation is considered to be the most suitable method for the determination of arsenic in water, yet a recent paper indicates that about 22% of arsenic has been reported as undetected by the hydride generation technique.

  This article refers to "unidentified" forms of arsenic, which are typically organic arsenics. The gaseous hydride/atomic absorption spectroscopic methods operate on the principle that trivalent arsenic is converted to its volatile hydride (arsine). This analytical method measures only inorganic arsenic in drinking water, as it is incapable of detecting non-hydride species. The focus of the document is on inorganic forms of arsenic, since this is the form typically found in water. The EPA-approved method is well proven to detect arsenic in drinking water.

- Practical quantitation limits should be provided for the following methods: graphite furnace atomic absorption spectroscopy in combination with high-pressure liquid chromatography, selective ion monitoring with inductively coupled plasma mass spectroscopy and stabilized temperature platform graphite furnace atomic absorption.

  The PQL for all three methods is 3 µg/L. This information has been added to the text.

- Standard Method reference numbers should be provided for the methods discussed in this section.

  The requested information has been added to the text in tabular form.

- Although speciation testing is recommended in Section 6.2, no information is provided in Section 5.0 regarding analytical methods for speciation.

  Information on speciation has been added to the Analytical Methods section.

- More guidance is required in the document to address lab variability issues and how to better interpret the range of limitations.

  This is outside the scope of this document. Variability is an implementation issue that is best dealt with by the authorities having jurisdiction.

- More guidance is necessary regarding whether exceedances of the proposed guideline (i.e. 5 or 10 µg/L) should trigger more frequent monitoring (i.e. quarterly, etc.) to assess seasonal changes and/or address issues related to the variability of results.

  General monitoring information has been provided in Section 3.0. Specific monitoring regimes are beyond the scope of this document. The U.S. EPA document entitled "Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final Rule (66FR6976) - Appendix B" may provide the guidance sought.

- This section indicates that inductively coupled plasma mass spectroscopy has limitations and may not be useful for routine monitoring. As this method is included in Standard Methods as an applicable method and is used by numerous laboratories, specific information on what the limitations are and why this method may not be useful for routine monitoring should be provided.

  Inductively coupled plasma mass spectroscopy analysis may be subject to chloride interference when samples contain high levels of chloride. This method also requires a high level of skill and operator training, and the high initial cost of instrumentation may prevent smaller labs from using this method due to operational and financial considerations. A table listing the advantages and disadvantages of standard EPA analytical methods for arsenic has been added to the document.

  Treatment Technology

- The recommendation for testing for general chemistry and type and concentration of arsenic in the water is a good one. However, there should be some general cautions added concerning interference with arsenic removal by certain metals and humic substances.

  Additional information has been provided in the treatment section to ensure better understanding of the issues related to interference with arsenic removal.

- This section notes that pre-treatment may be necessary to remove competing ions such as iron, sulphate and silicate, as well as total dissolved solids. It is important that stakeholders be advised that if their water quality exceeds the values for any of the noted parameters, pre-treatment or a combination of treatment units may be necessary. The importance of water quality testing and of pre-treatment to meet device input parameter speciations should be clarified and emphasized in the document much more than is already done.

  Additional information has been provided in the treatment section to ensure better understanding of the issues related to potential water quality differences.

- The document should clarify and explain why speciation testing is necessary for the determination of residential-scale treatment; comment on the availability of labs that do routine speciation testing and the testing method; and clarify and explain why testing to determine competing ion levels is necessary for the determination of residential-scale treatment.

  Clarification has been added regarding the issue of speciation. Pre-treatment (oxidation) is recommended rather than speciation, as the cost- and time-effectiveness of speciation are not clear. The availability of labs to do routine testing is outside the scope of this document.

- Distillation units are certified to reduce arsenic only to 0.05 mg/L, not to 0.01 mg/L, as noted in the document.

  Clarification has been added.

- The text indicates that devices certified as reducing the concentration of arsenic from 0.05 to 0.01 mg/L are intended specifically for treating water previously treated by municipal facilities. Why can these units not be used for private well supplies that have influent arsenic levels less than 0.05 mg/L?

  These devices can now be used on water with lower influent levels of arsenic and thus can also be used for private wells. The text has been revised to reflect this change.

- Treatment costs are not dealt with explicitly.

  It is not within the scope of this document to include specific treatment costs.

- It is unclear what the implications of the proposed standard are for smaller communities (e.g. First Nations communities), where the skills and technical background of the operating staff responsible for local water supplies are often a major challenge.

  Operational issues are best addressed through operator training and certification programs.

- The discussion document does not address in sufficient detail the topic of quality control. The smaller the population being served, the greater the challenges involved in obtaining reliable and realistic analytical data.

Accreditation of commercial laboratories ensures reliable and realistic analytical data. The accreditation process, which includes audits, ensures that validated methods are used and that Good Laboratory Practices, quality assurance and quality control are followed.

Health Effects

- Using studies with "methodological weaknesses" such as the Mexico study does not strengthen the document.

  The study has been removed from the document, and more recent relevant references have been added.

- The EPA and AWWARF report entitled "Cancer Risks Associated with Elevated Levels of Drinking Water Arsenic Exposure" concluded that arsenic in drinking water at levels above 10 µg/L was not associated with greater mortality from bladder or lung cancer, nor was a higher level of arsenic associated with a greater incidence of bladder or lung cancer.

  This study has limitations. The authors concluded that 1) analysis of bladder cancer mortality is limited, since people with bladder cancer do not die from it; 2) the latency period between arsenic exposure and death from cancer is relatively long (yet specific length is unknown), and, therefore, migration and death from other causes may mask health outcomes from arsenic exposure; and 3) an ecological study relates exposures and outcomes in groups of individuals that may not be representative of individual responses to arsenic exposure. The weight of evidence still lies with the epidemiological studies in Taiwan; Chen et al. (1985, 1992) have remained the key studies for the updated arsenic drinking water guideline. The new EPA and AWWARF (2004) study may serve to alleviate concerns related to exceeding the MAC.

- Indicating that "the form of arsenic that is responsible for influencing tumour formation is still not known" supports the limits of science and makes one question why "carcinogenicity is considered to be the critical effect for derivation of the guideline."

  Since the mechanism of action for arsenic is not yet known, the supporting document does not assume that one form of arsenic is more toxic than another form. Some new evidence suggests that organic arsenic may be more toxic than inorganic arsenic; however, further research is required to confirm these findings. Carcinogenicity is considered the critical effect, since arsenic is classified as a documented human carcinogen by Health Canada, IARC, and the U.S. EPA.

- Models of arsenic-induced cancer in the organs of experimental animals should be referenced in the report.

  Even though good animal models exist, it would be of little added value to reference them in the document, since they cannot be used for human risk assessment.

- The Shirachi et al. (1986) study should not be cited because it is negative and has been replaced in utility by the Yamamoto et al. (1995) study, which gave more positive results in a multi-organ initiation-promotion protocol.

  The relevant paragraph has been reworded, the Shirachi et al. (1986) reference has been deleted, and additional references have been added.

- The National Academy of Sciences expert panel concluded in its 2001 update on arsenic in drinking water that the science on arsenic suggests that it does not cause bladder and lung cancer at concentrations up to 50 ppb in drinking water.

  The 2001 update on arsenic in drinking water concluded that chronic arsenic exposure is associated with an increased incidence of lung and bladder cancer at levels below 50 µg/L. It concluded that the southwestern Taiwanese data remain as the preferred data for use in quantitative risk assessment. New epidemiological studies reviewed in the update can be used to support the Taiwanese data, although many have shortcomings, including biases, small sample sizes, potential confounders, and other limitations. More research on exposure to low levels of arsenic is required.

- Reports by independent expert panels, including the NAS, the U.S. National Drinking Water Advisory Council, and the U.S. EPA Science Advisory Board confirmed arsenic as a "suspected" carcinogen.

  Arsenic is classified as a documented human carcinogen (Group 1 carcinogen) by Health Canada and IARC and has, therefore, been assessed as a human carcinogen. The U.S. EPA classifies arsenic as a muti-route human carcinogen by the drinking water route.

- Steinmaus et al. (2003) and Lamm et al. (2004) found no association between bladder cancer risk and the high level (100 ppb) of arsenic exposure; the researchers concluded that there are no increased risks for arsenic intakes greater than 80 µg/day and that the risks are below predictions based on the Taiwanese studies. These studies suggest that the EPA's current risk assessment for arsenic is based on flawed interpretation of data from Taiwan that overpredict the cancer risk for arsenic in drinking water in the United States.

In the case of Lamm et al. (2004), the use of bladder cancer mortality data as the only endpoint for assessing cancer risks from arsenic exposure is limited, since many people with bladder cancer do not die from it. The authors indicate that further confirmatory work is needed. Both studies have been added to the supporting document.

Classification and Assessment

- The National Research Council's report entitled "Arsenic in Drinking Water (2001 Update)" presents sound recommendations for the assessment of risk for exposure to inorganic arsenic and should be considered vigilantly. In general, the Health Canada document does not fully consider the recommendations presented by the 2001 Update. Additionally, multiple manuscripts in the areas of epidemiology, kinetics and metabolism, mechanism of action, and treatment technologies regarding arsenic have been published since the release of the 2001 Update.

The quantitative risk assessment has been revised to incorporate the entire southwestern Taiwanese population as a comparison population, as recommended in the U.S. NRC 2001 update.

Economic Considerations

- In many areas of Canada, the existing groundwater has arsenic levels below or sometimes very near the proposed 0.005 mg/L guideline. The proposed new MAC for arsenic could result in higher treatment capital and operational costs if water suppliers had to meet the new guideline. Maintenance and operation of new facilities that require technical expertise to ensure water supply safety are a concern, as well as acquiring and maintaining qualified staff, equipment, and parts.

The Committee's final decision always considers cost implications and treatment and analytical capabilities, as well as health implications. After taking all available information into consideration, the Committee has decided to reduce the MAC from 0.025 to 0.01 mg/L.

If You Have Questions or Comments

If you have any questions or comments on the arsenic drinking water document, please contact:

Water Quality and Health Bureau
Safe Environments Programme
Healthy Environments and Consumer Safety Branch
Health Canada
269 Laurier Ave West
3rd Floor, A.L. 4903A
Ottawa, Ontario
K1A 0K9

Tel.: 613- 948-2568
Fax: 613-952-2574
E-mail: water_eau@hc-sc.gc.ca