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Arsenic Human Health Criteria Issues

I. General Information on Arsenic

Arsenic occurs naturally in rocks, soil, water, air, plants and animals. It can be further released into the environment through natural activities such as volcanic action, erosion of rocks and forest fires, or through human actions. Approximately 90 percent of industrial arsenic in the U.S. is currently used as a wood preservative, but arsenic is also used in paints, dyes, metals, drugs, soaps and semi-conductors. High arsenic levels can also come from certain fertilizers and animal feeding operations. Industry practices such as copper smelting, mining and coal burning also contribute to arsenic in our environment.

Arsenic may exist in both an organic and inorganic form, either in the trivalent or pentavalent state. Arsenic usually occurs in waters as inorganic oxides in the pentavalent form. Trivalent forms of arsenic (inorganic and organic) are more toxic to humans and aquatic organisms and are usually only present under anaerobic conditions.

Sources of human exposure to arsenic compounds may include air, soil, water and food. Water quality criteria may be established to protect consumption of water and/or fish.

II. Human Health Protection Under CWA and SDWA

The Environmental Protection Agency (EPA) Office of Water has established guidance or regulations for arsenic under the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA).

A. Ambient Human Health Criteria Under CWA

Under the CWA, a water quality criterion for arsenic - fish consumption was established at 0.14 ppb in 1992 using the hazard assessment in EPA's Integrated Risk Information System (IRIS) database (U.S. EPA, 1998) according to the 1980 methodology for developing ambient water quality criteria for human health. The criterion for water and fish consumption is 0.018 ppb. These arsenic water quality criteria represent a one in one million (10^{-6}) cancer risk level for arsenic exposures, and apply as inorganic arsenic only.

The EPA risk assessments for ambient arsenic human health criteria were based on the epidemiology study in Taiwan by Tseng et al. (1968) and Tseng (1977) for the prevalence of skin cancer. EPA used the evidence of skin cancer reported in the Taiwan study as the basis for the arsenic hazard and dose response assessment. Using a time- and dose- dependent multistage model which assumes that any exposure to a compound such as arsenic could result in a cancer response, the cancer potency (q1*) estimated for ingested arsenic is 1.75 mg/kg/day. The carcinogenic potency estimate or the slope

factor represents the upper bound cancer-causing potential resulting from lifetime exposure to a substance, arsenic in this case. The ambient human health criteria for arsenic were calculated based on a cancer risk level of 10^{-6} for a 70 kg person with a default fish and shellfish consumption of 6.5 gm/day (the 2000 Human Health Methodology changed the default fish consumption value for the general population to 17.5 gm/day) using the estimated carcinogenic potency estimate or slope factor of 1.75 per mg/kg-day [Appendix A shows the calculation]. Also, the bioconcentration factor (the ratio of the contaminant concentration in fish tissue versus that in water) of 44 L/kg is used to convert the tissue concentration to the water column concentration.

A bioconcentration factor (BCF) relates the concentration of a chemical in aquatic animals to the concentration in the water in which they live. An appropriate BCF can be used with data concerning food intake to calculate the amount of arsenic which might be ingested from the consumption of fish and shellfish. Residue data for a variety of inorganic compounds indicate that bioconcentration factors for the edible portion of most aquatic animals are similar, except that for some compounds bivalve molluscs (clams, oysters, scallops, and mussels) should be considered a separate group.

The 1984 criteria document for arsenic (EPA, 1985) contains BCFs for fish and invertebrates. The BCFs were calculated from whole body measurements and range from 0 to 4 (EPA, 1985). Results for invertebrates ranged from 0 to 17. Spehar, et al. (1980) obtained bioconcentration factors of zero for four different arsenic compounds in rainbow trout, but a BCF of 4 was obtained with the bluegill (U.S. EPA, 1980). Thus, the average BCF for arsenic is probably close to 1.0 for aquatic fish species. The BCF of 350 was obtained for sodium arsenite with in oysters. EPA used the values of 350 (for oysters) and 1 to derive a weighted average (weighted with consumption rate) bioconcentration factor 44 L/kg.

B. MCL Under SDWA

Following the 1976 enactment of the SDWA, EPA proposed, as part of the National Interim Primary Drinking Water Standards, an interim MCL of 50 ppb for arsenic. The U.S. Public Health Service originally set the 50-µg/L standard in 1942. In 1988, EPA conducted a risk assessment for arsenic in drinking water (U.S. EPA, 1988). In 1996, EPA requested that the National Research Council (NRC), the operating arm of the National Academy of Sciences and the National Academy of Engineering, independently review the scientific database and evaluate the scientific validity of that risk assessment. In response to that request, the NRC published *Arsenic in Drinking Water* in 1999.

To incorporate the most recent scientific research into its decision, on January 22, 2001 EPA adopted a new standard for arsenic in drinking water at 10 ppb, replacing the old standard of 50 ppb. The rule became effective on February 22, 2002. The date by which systems must comply with the new 10 ppb standard is January 23, 2006. The human health risk assessment for the derivation of 10 ppb used more recent Taiwan studies on bladder and lung cancer data (Chen et al, 1988, 1992; Wu et al., 1989).

In the context of SDWA implementation, MCLs define the maximum permissible level of a contaminant in water that may be delivered to a user of a public water system. Consistent with SDWA requirements, the MCLs for arsenic are set based on not only human health risk assessment information, but also other factors such as treatment costs and benefits, as well as analytical detection limits.

EPA based the MCL on total arsenic, because drinking water contains almost entirely inorganic forms, and the analytical methods for total arsenic are readily available and capable of being performed by certified laboratories at an affordable cost.

Iowa currently has a drinking water standard of 10 ppb that is consistent with the MCL value for arsenic.

III. Iowa's Proposed Human Health Criteria Revision

The current EPA human health criteria (0.14 ppb for fish consumption only and 0.018 ppb for both fish and water consumption) are calculated for a risk level of 10^{-6}. Risk levels of 10^{-5}, 10^{-6}, and 10^{-7} are often used by States as minimal risk levels in interpreting the human health standard. In Iowa, the human health criteria for carcinogenic parameters are based on the prevention of an incremental cancer risk level of 10^{-5}. For noncarcinogenic parameters, Iowa adopted the recommended EPA criterion directly. Since arsenic is classified as a potential carcinogen, Iowa is proposing the following criteria changes for human health protection: changing the human health criterion of 50 ppb to 1.4 ppb for fish consumption only; no changes for the current 0.18 ppb for consumption of both fish and water.

IV. Other States Human Health Criteria

Table 1 shows the current ambient human health criteria for arsenic in several states.

Table 1. Arsenic Human Health Criteria for Other States

States	Arsenic Human Health Criterion (non water supply)	Drinking Water (ppb)
Nebraska	16.7	10
Kansas	0.14[a]	10
Missouri	None	50
Minnesota	53	2.0
Illinois	None	50
Iowa	50	10

a. EPA promulgated criterion

EPA had withdrawn the federal human health water quality criteria for arsenic applicable to Idaho and Alaska.

In l992, EPA promulgated a final rule (known as the National Toxics Rule) to establish numeric water quality criteria for 12 States and 2 Territories that had failed to comply fully with section 303(c)(2)(C) of the Clean Water Act (57 FR 60848). The criteria, codified at 40 CFR 131.36, became the applicable water quality standards in those 14 jurisdictions for all purposes and programs under the Clean Water Act effective February 5, l993. When a State adopts criteria that meet the requirements of the Clean Water Act, EPA withdraws its criteria. Idaho adopted human health criteria for arsenic (0.020 ppb for the consumption of water and organisms and 6.2 ppb for the consumption of organisms); these criteria are less stringent than the federal regulations (0.018 ppb for the consumption of water and organisms and 0.14 ppb for the consumption of organisms). Idaho's criteria for arsenic differ from the federal criteria because the State used a bioconcentration factor (BCF) to derive its criteria that is different from the BCF used by EPA. Idaho selected a BCF that the State believes more accurately reflects the species of fish present in State's surface waters. Having reviewed Idaho's submission, EPA concluded that the State's choice of a BCF to calculate the arsenic criteria was appropriate and the State's arsenic criteria met the requirements of the Clean Water Act.

A similar situation occurred in Alaska. EPA withdrew the promulgation to Alaska's on May 21, 1997. Subsequent to the promulgation of the NTR, a number of issues and uncertainties arose concerning the health effects of arsenic. EPA determined that these issues and uncertainties were sufficiently significant to necessitate a careful evaluation of the risks of arsenic exposure. Accordingly EPA has undertaken a number of activities aimed at reassessing the risks to human health from arsenic. In light of EPA's review of the health effects of arsenic, the State of Alaska has proposed that the Safe Drinking Water Act (SDWA) maximum contaminant level (MCL) for arsenic of 50 ppb currently in the state's water quality standards be used as meeting the requirements of the Clean Water Act in lieu of the current human health criteria in the NTR. As adopted by Alaska, the MCL for arsenic applies to all fresh waters that have the public water supply designated use. EPA found that the MCL for arsenic in freshwaters designated for public water supply, in conjunction with Alaska's aquatic life criteria for arsenic, meets the requirements of the CWA, and accordingly proposes to withdraw the applicability to Alaska of the human health criteria for arsenic promulgated in the NTR.

Also, EPA Region 6 established an interim strategy for Arsenic - Freshwater Human Health Criterion for Fish Consumption because of the uncertainties associated with the current 304(a) human health criterion. The interim strategy recommends the human health criterion for total arsenic of 20.5 ppb, which was derived using a bioconcentration factor of 1 L/kg (provided in the draft version of the Great Lakes Initiatives) instead of 44 L/kg that used to derive the national criterion. The interim strategy also assumes 30 percent of total arsenic in fish tissue is inorganic.

V. Options for the Criteria

The current 304(a) criteria were developed based on the Taiwanese study conducted in the late 60's and 70's of skin cancer risk. Since then, new toxicity data have become available. EPA is in the process of revising the recommended human health ambient

water quality criteria for arsenic. The revision effort is focusing on the arsenic bioaccumulation factor, and the cancer potency estimate based on new toxicity data search. Also, the current 304(a) human health criteria were derived based on the 1980 methodology. EPA published the 2000 Human Health Methodology, which bridges the gap between the differences in the risk assessment and risk management approaches used by EPA's Office of Water for the derivation of AWQC under the authority of the CWA and Maximum Contaminant Level Goals (MCLGs) under the Safe Drinking Water Act (SDWA). Research has shown that different states and EPA Regions have taken approaches that deviate from the current 304(a) human health criteria for arsenic. The following summarizes the different approaches currently approved by EPA.

- Several states including Missouri, Illinois, and Alaska adopted the drinking water standard of MCL 10 ppb for water supply uses. Based on this approach, Iowa could revise the current human health criterion of 50 ppb for fish consumption to 10 ppb in order to be consistent with the drinking water standard. As stated earlier, EPA found that for State of Alaska the MCL for arsenic in freshwaters designated for public water supply, in conjunction with aquatic life criteria for arsenic, meets the requirements of the CWA.

- The EPA 304(a) arsenic criterion of 0.14 ppb for human health was calculated based on a BCF value for oysters and bluegill. Research data found that bivalve mollusks are high bioaccumulable species in comparison to freshwater fish. EPA Region 6 recommended an arsenic human health criterion for fish consumption of 20.5 ppb in its interim strategy for arsenic (U.S. EPA Region 6, 2007). The value is recalculated based on BCF of 1 L/kg from the Great Lakes Initiatives and assumes 30% of total arsenic in fish tissue is inorganic. The State of Idaho recalculated the human health criteria based on site specific BCF and adopted a human health criterion of 6.2 ppb for fish consumption. This criterion was approved by EPA. Based on this approach, Iowa could recalculate the human health criterion based on fish species present in Iowa waters.

Due to the fact that EPA has approved at least 2 different options for setting arsenic criteria, it may be prudent to re-evaluate Iowa's arsenic criteria based on the previous EPA approvals or delay the arsenic human health criteria rule making until EPA finishes the review and development of the 304(a) human health criteria for arsenic. In the meantime, Iowa would adopt the 304(a) criteria for aquatic life protection and continue to apply the adopted EPA 304(a) criterion for both fish and water consumption value of 0.18 ppb for Class C Drinking Water uses.

If Iowa continues the rulemaking process for the proposed human health criterion of 1.4 ppb for arsenic (fish consumption only) and then updates the value when EPA finalizes the new human health criteria review, future implementation problems may occur. If EPA review results in a less stringent criterion, it could cause antidegradation and backsliding issues with NPDES permit limits in addition to the unnecessary cost to impacted communities.

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Appendix A: Derivation of AWQC for Human Health

1980 Methodology Calculations

Using cancer potency, q1*:

For consumption of water and organisms:

$$AWQC[ug/L] = \frac{10^{-6} \times 70\,kg \times 1000\,ug/mg}{ql^* \times [kg - d/mg] \times (2\,L/d + (0.0065\,kg/d \times BCF\,[L/kg]))}$$

For consumption of organisms only:

$$AWQC[ug/L] = \frac{10^{-6} \times 70\,kg \times 1000\,ug/mg}{ql^* \times [kg - d/mg] \times 0.0065\,kg/d \times BCF\,[L/kg]}$$

AWQC = Ambient water quality criteria = national recommended water quality criteria

q1* = Cancer potency factor kg-d/mg or per mg/kg-day

DI = Drinking water intake 2 L/day

BW = Human body weight 70 kg

FI = Fish intake 0.0065 kg/day

BCF = Bioconcentration factor L/kg