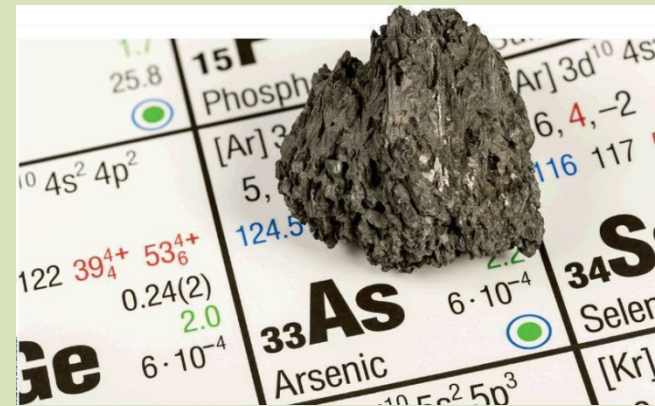


Negotiated Rulemaking
Docket No. 58-0102-1801

Update to Human Health Criteria for Arsenic

April 19, 2018



Objectives

- Background
- Refresher on how human health criteria are derived
- Frame issues related to HHC for Arsenic
 - Challenges to deriving appropriate criteria

RULEMAKING SCHEDULE

Water Quality Standards
Human Health Criteria for Arsenic
Docket No. 58-0102-1801

Action	Date
Notice of Negotiated Rulemaking published in Idaho Administrative Bulletin	4/4/18
1 st negotiated rulemaking meeting	4/19/18
Deadline for submitting Proposed Rule to Office of Administrative Rules for publication in the Bulletin	8/3/18
Proposed Rule published in Bulletin; comment period begins	9/5/18
End of comment period.	10/5/18
Mail final proposal to Board members	10/31/18
Board meeting – consideration of final proposal for adoption of pending rule	11/14&15/18
Notice of Adoption of Pending Rule published in Idaho Administrative Bulletin	1/2/19
Pending rule reviewed by Legislature	1/19
Pending rule becomes final and effective if approved by Legislature	2019 sine die

This rulemaking schedule is subject to change.

Outline

- Background
 - Why we're here
 - General background on calculating human health criteria
 - History of Arsenic criteria in Idaho
- Issues to consider
 - Revisions to IRIS
 - Inorganic vs. Organic forms of As
 - Natural Background Concentrations of Arsenic in Surface Water
 - Disconnect between CWA and SDWA
 - Bioaccumulation

Outline

- Potential Approaches
 - Idaho's HHC calculations
 - EPA's Recommended Criteria
 - Oregon's 2011 Criteria
- Next Steps

Why are we updating?

- Current criteria based on the SDWA MCL
 - 10 µg/L for both Fish Only and Fish + Water
- Submitted and approved by EPA in 2010

Why are we updating?

- May 2016 – EPA entered consent decree with NWEA to reconsider the 2010 approval
- September 2016 – Disapproval of 10 µg/L criteria
 - Basis – EPA did not follow federal regulations or its own guidance when approving MCL as CWA criteria
 - Consent decree requires EPA approval, or federal promulgation, by July 15, 2019

Remedy to Address EPA's Disapproval

- Adopt protective As criteria (without feasibility considerations)
- Review EPA's final IRIS Toxicological Review of Inorganic Arsenic (anticipated in 2017) and take into account when deriving criteria
 - IRIS review is still not available for consideration for this rulemaking

EPA Recommendation

- Current recommendation unchanged since 1992 National Toxics Rule

How HHC are Calculated

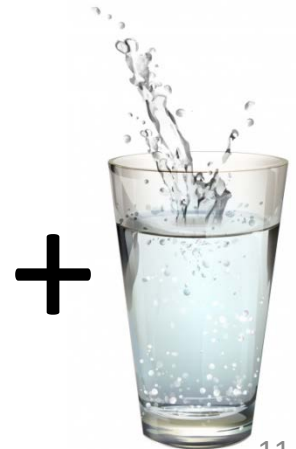
Human Health

Recreation

Domestic Water
Supply

Fish Only

Fish + Water



Human Health

- Based on lifetime exposure to human toxins
- Uses population estimates of body weight, drinking water intake, and fish consumption
- Uses incremental cancer risk
- Uses chemical specific properties
 - Cancer Potency Factor – how carcinogenic?
 - Bioaccumulation factor

Carcinogens

BW = Human Body Weight (kg)

Estimate taken from the distribution of body weights for the target population – typically the mean of the population

$$AWQC = RSD * \left(\frac{BW}{DI + (FI * BAF)} \right) * 1000$$

RSD = Risk-specific dose

$$\left(\frac{\textit{Target Incremental Cancer Risk}}{\textit{Cancer Slope Factor}} \right)$$

DI = Drinking Water Intake (L/day)

Estimate taken from the distribution of water consumption (from all sources) for the target population. Typically from the upper end of the distribution.

FI = Fish Ingestion (or Fish Consumption Rate) kg/day

Estimate taken from the distribution of fish consumption for the target population.

BAF = Bioaccumulation Factor

Accounts for the accumulation of a pollutant in the tissue of fish that the target population may consume

Carcinogens

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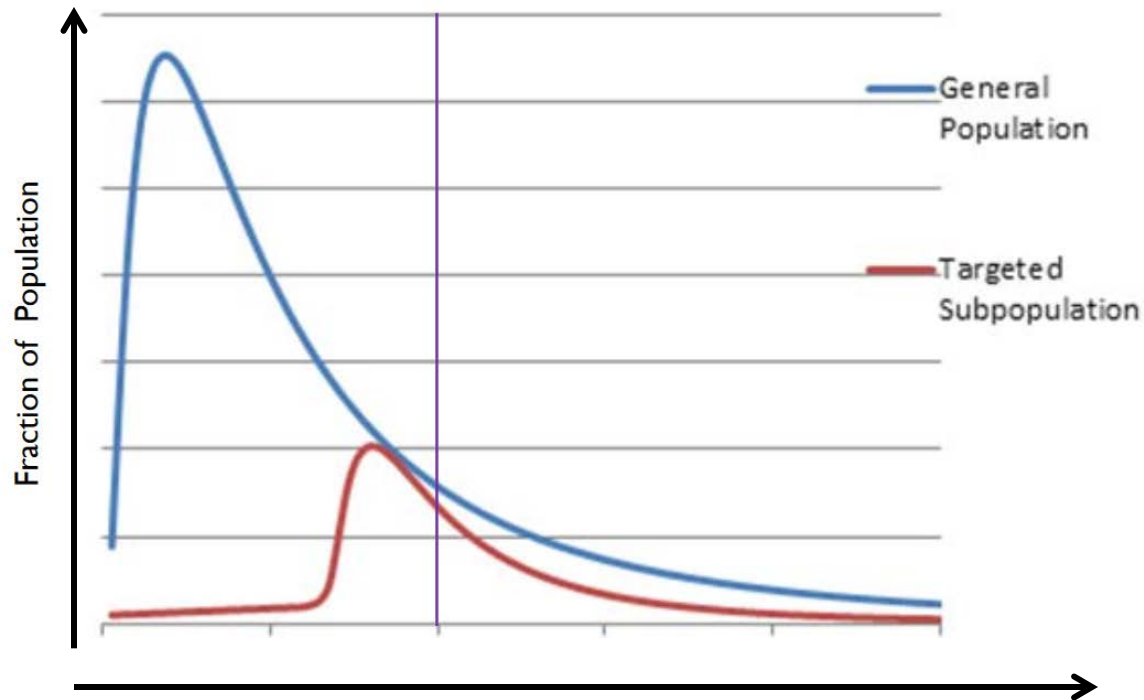
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Accounts for the accumulation of a pollutant in the tissue of fish that the target population may consume

Human Health



Body Weight (BW)
Drinking water intake (DI)
Fish consumption (FI)

$$AWQC = RSD * \left(\frac{BW}{DI + (FI * BAF)} \right) * 1000$$

Human Health

- Carcinogens:
 - Risk Specific Dose (RSD): the dose that results in an incremental cancer risk at the target risk factor

$$RSD = \frac{\textit{Target Incremental Cancer Risk}}{\textit{Cancer Slope Factor}}$$

- Cancer risk factor: number of new cancers that may result in a population due to an increase in exposure
 - 10^{-5} cancer risk level equates to 1 new cancer in a population of 100,000

Human Health

- Bioaccumulation: BCF or BAF
 - BCF – direct uptake from water
 - BAF – includes dietary contribution
- For highly bioaccumulative chemicals, makes little difference for Fish Only vs. Fish + Water, since fish carry high exposure. But for relatively non accumulative, the consumption of water may be largest contributor

History of Arsenic HHC in Idaho

Arsenic Human Health Criteria				
Date	Action	Fish Only (µg/L)	Fish + Water (µg/L)	Notes
December 22, 1992	EPA promulgation of the National Toxics Rule (NTR), includes As criteria for human health	0.14	0.018	Based on fish consumption rate of 6.5 g/day, drinking water intake of 2 L/day, BW of 70 kg, and BCF of 44. These federally promulgated criteria become effective for Clean Water Act Purposes in Idaho
August 24, 1994	Idaho adopts NTR into state WQS by reference			

History of Arsenic HHC in Idaho

Arsenic Human Health Criteria				
Date	Action	Fish Only (µg/L)	Fish + Water (µg/L)	Notes
March 8, 1995	Idaho As criteria revised by State Legislature	6.2	0.02	Revised Fish Only criterion using BCF of 1, rounded Fish + Water criterion up from 0.018
June 25, 1996	EPA approves Idaho adoption of NTR and revised As criteria			
November 10, 1997	EPA final Federal rule removing Idaho from the NTR for As becomes effective			Idaho criteria adopted in 1995 become effective for Clean Water Act purposes

History of Arsenic HHC in Idaho

Arsenic Human Health Criteria				
Date	Action	Fish Only (µg/L)	Fish + Water (µg/L)	Notes
March 19, 1999	Idaho adoption of revised As criteria based on current (1999) SDWA MCL approved by state legislature	50	50	Submitted for EPA approval April 23, 1999. Criteria were effective for Clean Water Act purposes upon effective date of final rule; EPA did not act on this submittal until 2016 disapproval.
January 22, 2006	SDWA MCL for drinking water reduced from 50 µg/L to 10 µg/L becomes effective			

History of Arsenic HHC in Idaho

Arsenic Human Health Criteria				
Date	Action	Fish Only (µg/L)	Fish + Water (µg/L)	Notes
March 29, 2010	Idaho adoption of revised As criteria based on SDWA MCL approved by state legislature	10	10	Submitted for EPA approval June 21, 2010. Approved by EPA July 7, 2010; effective for Clean Water Act purposes
September 15, 2016	EPA disapproval of previously approved As criteria			

EPA approval, or federal promulgation, by July 15, 2019

- Idaho has held off on rulemaking in anticipation of revised National Recommendation update to IRIS Toxicological Review of Inorganic Arsenic
 - Uncertainty about: toxicity of inorganic As, what is an appropriate BAF/BCF, what is protective
- Engaged in rulemaking now in response to Federal Rulemaking

Status of EPA Recommendations

- EPA develops recommended criteria for states to consider
 - 304(a) criteria for As for human health

Status of EPA Recommendations

- 1980: EPA recommended surface water criteria for three different risk levels: 10^{-7} , 10^{-6} , 10^{-5}

	10^{-7}	10^{-6}	10^{-5}
Fish Only ($\mu\text{g/L}$)	0.00175	0.0175	0.175
Fish + Water ($\mu\text{g/L}$)	0.00022	0.0022	0.022

- Based on Fish Consumption of 6.5 g/day, Water Consumption of 2 L / day, Body Weight of 70 kg

Status of EPA Recommendations

- 1984: EPA updated As criteria for Aquatic Life, HHC remain unchanged
- 1992: EPA National Toxics Rule

	10^{-6}
Fish Only ($\mu\text{g/L}$)	0.14
Fish + Water ($\mu\text{g/L}$)	0.018

CSF = 1.75*

FCR = 6.5 g/day

DI = 2.0 L/day

BCF = 44

Status of EPA Recommendations

- 2002 and 2015 updates to national toxics HHC recommendations revised FCR, BW, and DI

FCR = 22 g/day

BW = 80 kg

DI = 2.4 L/day

National BAFs

- Arsenic recommendations have not been updated to reflect these revisions nor the CSF

Federal Rulemaking

Issues to Consider

- No revision to IRIS or 304(a)
- Inorganic vs. Organic forms of As
- Natural Background Concentrations of Arsenic in Surface Water
 - Disconnect between CWA and SDWA
- Bioaccumulation

Inorganic vs. Organic As

- Inorganic is believed to be the more toxic form
- Criteria specific to inorganic arsenic
- Most data are for total arsenic
- BCF used in national recommendation based on total arsenic

**Arsenic, Mercury, and Selenium in Fish Tissue and Water
from Idaho's Major Rivers:
A Statewide Assessment**



Prepared by Don A. Essig



March 2010

Background As in Idaho Surface Waters

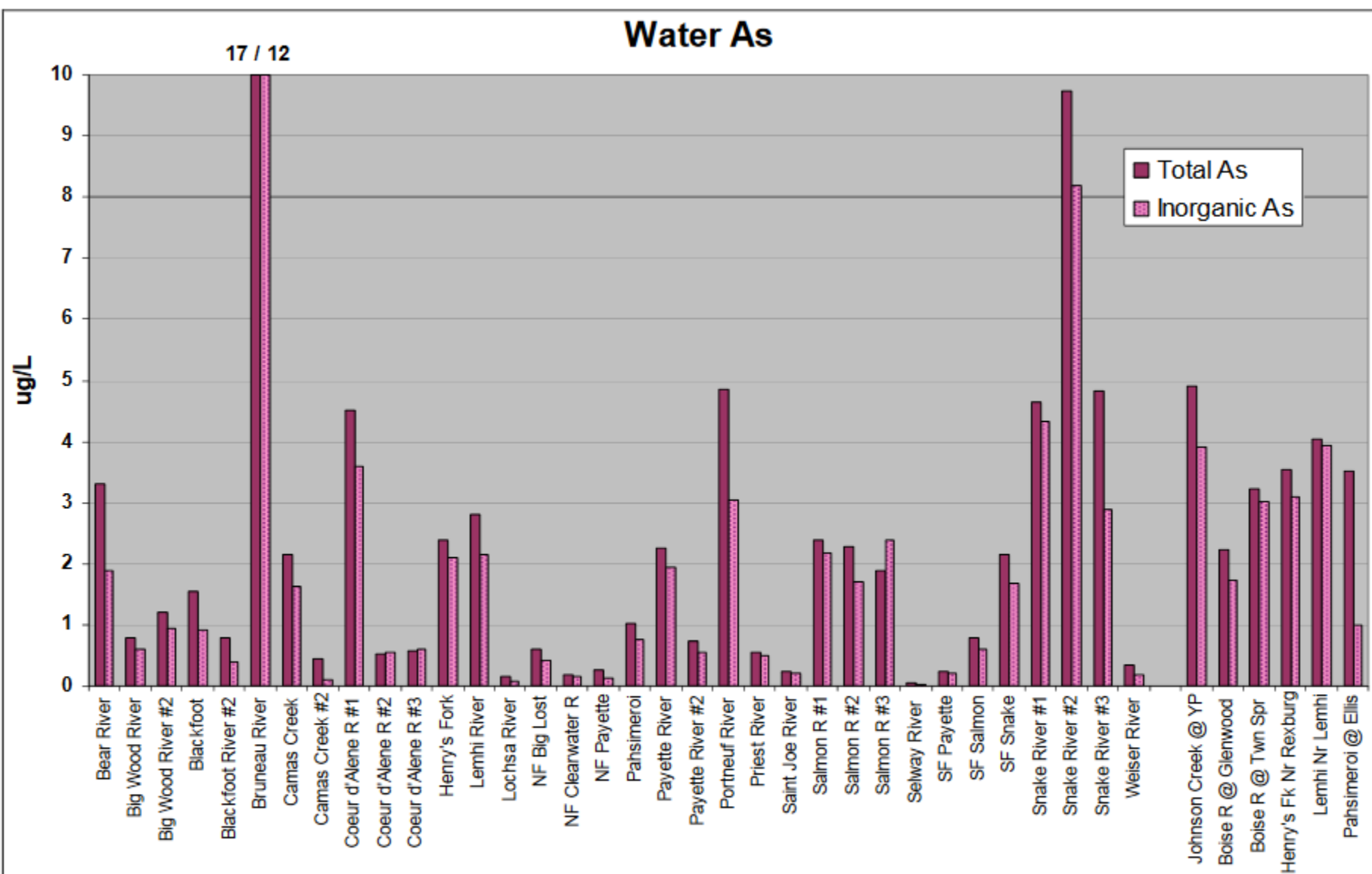
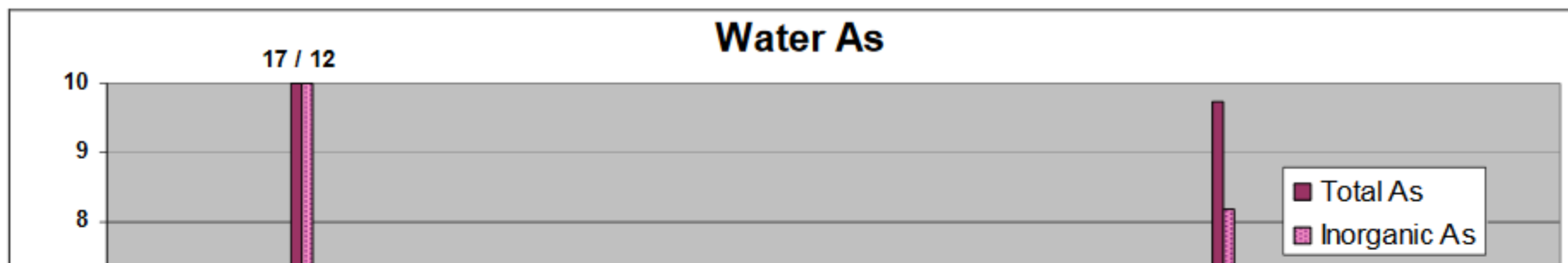


Figure 9. Total and Inorganic Arsenic (As) in Water (the first 34 sites shown are those that were planned for this study; the other six sites are those for which USGS provided samples)



Only two of the sites monitored had samples with concentrations less than the EPA-recommended arsenic criterion⁸ of 0.14 $\mu\text{g/L}$, which is recommended for protection of human health, applicable to cases in which the only route of exposure is the consumption of fish. No water samples had arsenic levels less than the companion criterion of 0.018 $\mu\text{g/L}$, which is recommended for cases in which exposure is both from drinking water and consuming fish from

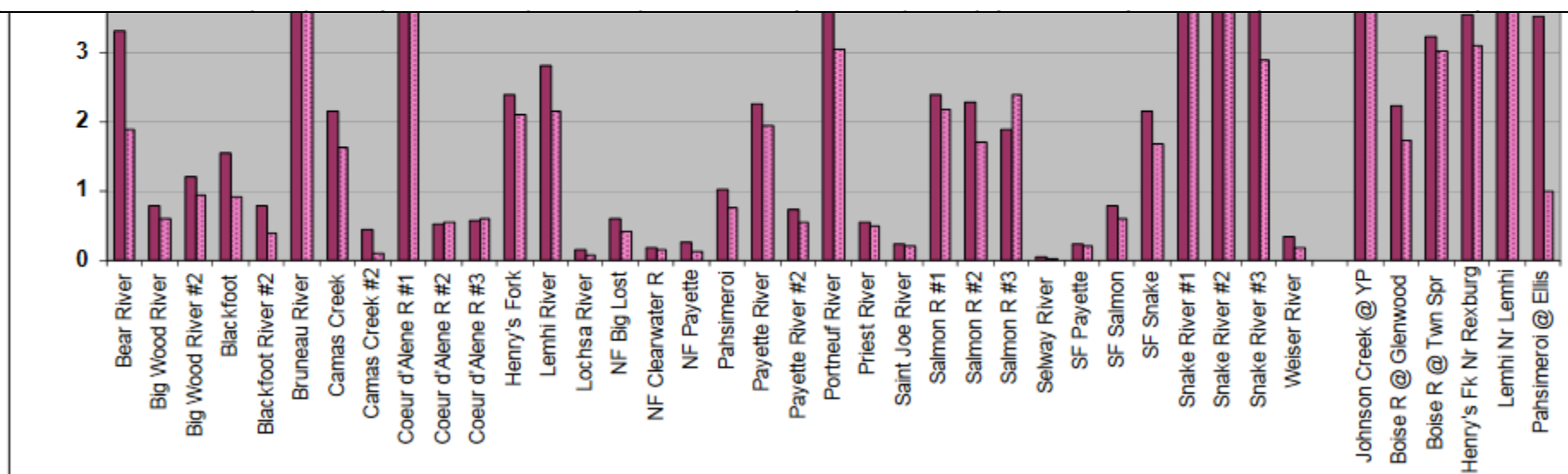


Figure 9. Total and Inorganic Arsenic (As) in Water (the first 34 sites shown are those that were planned for this study; the other six sites are those for which USGS provided samples)

Some Preliminary Statewide Data – USGS Lake / Stream

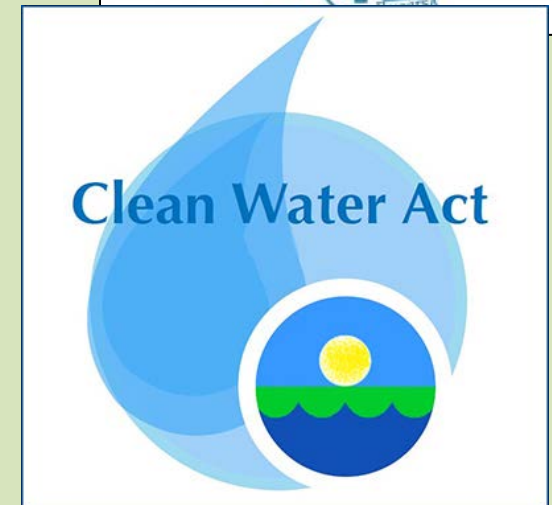
	USGS Total As (µg/L)	X0.78	Idaho Statewide Assessment inorganic As (µg/L)
Mean	1.5	1.2	1.75
Median	0.7	0.6	0.84
N	658		34

Implications

- Listing and TMDL
 - Developing TMDLs for naturally elevated pollutants is not an efficient use of resources
- Antidegradation
 - Waters listed as impaired for Recreation due to As exceedance would not be able to receive Tier II protection under Idaho antidegradation policy

SDWA vs CWA

- MCL = 10 $\mu\text{g/L}$
 - Water can be delivered as safe for drinking water, but cannot be discharged without treatment to reduce arsenic due to concerns about exposure from drinking water
- SDWA allows for consideration of treatability and economics, CWA does not



Some Preliminary Statewide Data – Ground Water

	SDWIS Total As µg/L	X0.78	IDWR Total As µg/L	X0.78
Mean	330	257.4	7.2	5.6
Median	8	6.2	2.7	2.1
10 th %ile	2	1.6	0.3	0.2
N	5,398		10,018	

Natural Background Provisions

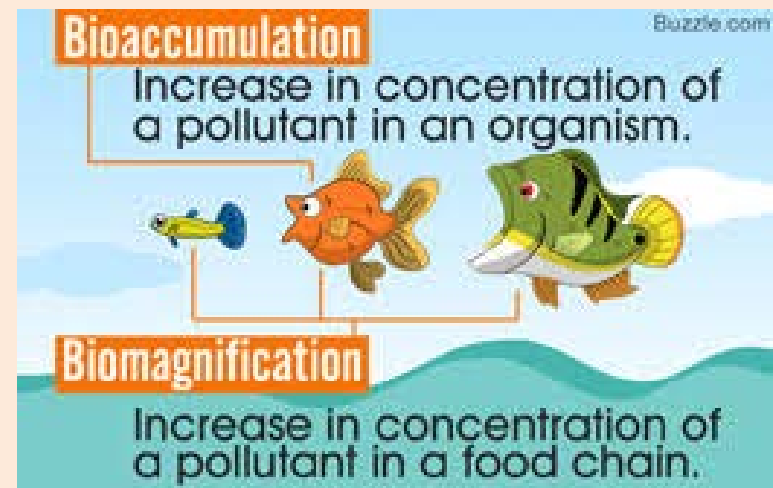
- **054.04. Natural Conditions.** *There is no impairment of beneficial uses or violation of water quality standards where natural background conditions exceed any applicable water quality criteria as determined by the Department, and such natural background conditions shall not, alone, be the basis for placing a water body on the list of water quality limited water bodies described in Section 055.*

Natural Background Provisions

200.09. Natural Background Conditions as Criteria. *When natural background conditions exceed any applicable water quality criteria set forth in Sections 210, 250, 251, 252, or 253, the applicable water quality criteria shall not apply; instead, there shall be no lowering of water quality from natural background conditions. Provided, however, that temperature may be increased above natural background conditions when allowed under Section 401.*

Bioaccumulation

- BCF – direct uptake from water (lab based)
- BAF – includes dietary uptake (field based)
- Calculated as the ratio of chemical in fish tissue vs. water
 - For arsenic often based on total arsenic



Bioaccumulation

- EPA's recommended criteria based on BCF of 44
 - Geomean from studies of Bluegill (BCF = 4) and Eastern Oyster (BCF = 350)



Bioaccumulation

- Idaho's 1995 criteria used a BCF of 1 to correct for total vs. inorganic arsenic and removal of Eastern Oyster
- Oregon 2011 criteria – reviewed BCF studies
 - For freshwater, used BCF of 14 based on 4 studies of freshwater finfish
 - Used a 10% Inorganic Proportion Factor to account for Total vs. Inorganic As

Bioaccumulation

- Idaho Statewide Assessment
 - Calculated BAFs
 - Total Arsenic – mean 143
 - Inorganic Arsenic – mean ≥ 11
- Water sample may not be temporally representative

Comparison of Approaches



$$AWQC = \frac{\text{Cancer Risk Factor}}{\text{Cancer Slope Factor}} * \left(\frac{BW}{DI + (FI * BAF * IF)} \right) * 1000$$

	Idaho 2015 HHC	EPA Recommended As Criteria	Oregon Freshwater As Criteria	
Target Incremental Cancer Risk	1 x 10 ⁻⁵	1 x 10 ⁻⁶	Fish only 1.1 x 10 ⁻⁵	Fish + water 1 x 10 ⁻⁴
Cancer Slope Factor	--	1.75	1.5	
Body Weight (kg)	80	70	70	
Drinking Water Intake (L/day)	2.4	2.0	2.0	
Fish Intake (kg/day)	0.0665	0.0065	0.175	
BCF	--	44	14	
Inorganic Proportion Factor (%)	--	--	10	

Potential Approaches

- Adopt EPA's Recommendation (from NTR)
 - Based on outdated Cancer Slope Factor (1.75*), FCR (6.5 g/day), BW (70 kg), and DI (2.0 L/day)
 - Questions related to BCF (44) applicability

Potential Approaches

- Follow Oregon Approach
 - Bifurcated cancer risk factor
 - Use literature-derived BCF (14), apply inorganic proportion factor
 - Would need to use updated Cancer Slope Factor, BW, DI, and FI
 - Although approved for OR, not assured of approval in Idaho

Potential Approaches

- Modify using Idaho Specific Inputs (based on 2015 HHC)
 - CSF = 1.5
 - BW = 80
 - DI = 2.4 L/day
 - FCR = 66.5 g/day
 - Cancer Risk Factor = 10^{-5}
- Identify appropriate BCF / BAF
- Inorganic Fraction?

Potential Approaches

- Modify using Idaho Specific Inputs (based on 2015 HHC)
 - Uncertainty about Exposure Inputs
 - No action on submittal of Idaho HHC to date
 - Uncertainty about appropriate BCF / BAF
 - Use of national BCF data?
 - Idaho-specific BAFs based on single water sample
 - Detection levels make calculation imprecise
 - Uncertainty about appropriate toxicity
 - IRIS update

Next Steps

- Comments due April 30
 - Preferred approach
 - Any other relevant information
- Next Rulemaking Meeting May 23
 - In depth BCF/BAF Discussion

