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**

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

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

• 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.

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.

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

RSD = Risk-specific dose
(Target Incremental Cancer Risk) / Cancer Slope Factor
BW = Human Body Weight (kg)
Estimate taken from the distribution of body weights for the target population – typically the mean of the population

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

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

RSD = Risk-specific dose
(Target Incremental Cancer Risk) / Cancer Slope Factor

Fl = Fish Ingestion (or Fish Consumption Rate) kg/day
Estimate taken from the distribution of fish consumption for the target population.
Human Health

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

\[ AWQC = RSD \times \left( \frac{BW}{DI + (FI \times BAF)} \right) \times 1000 \]
• Carcinogens:

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

\[
RSD = \frac{\text{Target Incremental Cancer Risk}}{\text{Cancer Slope Factor}}
\]

– 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
• 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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Fish Only (µg/L)</th>
<th>Fish + Water (µg/L)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 22, 1992</td>
<td>EPA promulgation of the National Toxics Rule (NTR), includes As criteria for human health</td>
<td>0.14</td>
<td>0.018</td>
<td>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</td>
</tr>
<tr>
<td>August 24, 1994</td>
<td>Idaho adopts NTR into state WQS by reference</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# History of Arsenic HHC in Idaho

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Arsenic Human Health Criteria</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 19, 1999</td>
<td>Idaho adoption of revised As criteria based on current (1999) SDWA MCL approved by state legislature</td>
<td>Fish Only (µg/L) 50</td>
<td>Fish + Water (µg/L) 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>January 22, 2006</td>
<td>SDWA MCL for drinking water reduced from 50 µg/L to 10 µg/L becomes effective</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# History of Arsenic HHC in Idaho

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

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: $10^{-7}$, $10^{-6}$, $10^{-5}$

<table>
<thead>
<tr>
<th></th>
<th>$10^{-7}$</th>
<th>$10^{-6}$</th>
<th>$10^{-5}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish Only (µg/L)</td>
<td>0.00175</td>
<td>0.0175</td>
<td>0.175</td>
</tr>
<tr>
<td>Fish + Water (µg/L)</td>
<td>0.00022</td>
<td>0.0022</td>
<td>0.022</td>
</tr>
</tbody>
</table>

• 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

<table>
<thead>
<tr>
<th></th>
<th>$10^{-6}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish Only (µg/L)</td>
<td>0.14</td>
</tr>
<tr>
<td>Fish + Water (µg/L)</td>
<td>0.018</td>
</tr>
</tbody>
</table>

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
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 criterion\(^8\) of 0.14 μg/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 μg/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

<table>
<thead>
<tr>
<th></th>
<th>USGS Total As (µg/L)</th>
<th>X0.78</th>
<th>Idaho Statewide Assessment inorganic As (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>1.5</td>
<td>1.2</td>
<td>1.75</td>
</tr>
<tr>
<td>Median</td>
<td>0.7</td>
<td>0.6</td>
<td>0.84</td>
</tr>
<tr>
<td>N</td>
<td>658</td>
<td></td>
<td>34</td>
</tr>
</tbody>
</table>
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 µg/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

<table>
<thead>
<tr>
<th></th>
<th>SDWIS Total As µg/L</th>
<th>X0.78</th>
<th>IDWR Total As µg/L</th>
<th>X0.78</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean</strong></td>
<td>330</td>
<td>257.4</td>
<td>7.2</td>
<td>5.6</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td>8</td>
<td>6.2</td>
<td>2.7</td>
<td>2.1</td>
</tr>
<tr>
<td><strong>10th %ile</strong></td>
<td>2</td>
<td>1.6</td>
<td>0.3</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>N</strong></td>
<td>5,398</td>
<td></td>
<td>10,018</td>
<td></td>
</tr>
</tbody>
</table>
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.*
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 =** \[
\frac{\text{Cancer Risk Factor}}{\text{Cancer Slope Factor}} \times \left( \frac{\text{BW}}{\text{DI} + (\text{FI} \times \text{BAF} \times \text{IF})} \right) \times 1000
\]

<table>
<thead>
<tr>
<th></th>
<th>Idaho 2015 HHC</th>
<th>EPA Recommended As Criteria</th>
<th>Oregon Freshwater As Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target Incremental Cancer Risk</strong></td>
<td>$1 \times 10^{-5}$</td>
<td>$1 \times 10^{-6}$</td>
<td>Fish only $1.1 \times 10^{-5}$</td>
</tr>
<tr>
<td><strong>Cancer Slope Factor</strong></td>
<td>--</td>
<td>1.75</td>
<td>1.5</td>
</tr>
<tr>
<td><strong>Body Weight (kg)</strong></td>
<td>80</td>
<td>70</td>
<td>70</td>
</tr>
<tr>
<td><strong>Drinking Water Intake (L/day)</strong></td>
<td>2.4</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td><strong>Fish Intake (kg/day)</strong></td>
<td>0.0665</td>
<td>0.0065</td>
<td>0.175</td>
</tr>
<tr>
<td><strong>BCF</strong></td>
<td>--</td>
<td>44</td>
<td>14</td>
</tr>
<tr>
<td><strong>Inorganic Proportion Factor (%)</strong></td>
<td>--</td>
<td>--</td>
<td>10</td>
</tr>
</tbody>
</table>

---

*BW* = Body Weight (kg)

*DI* = Drinking Water Intake (L/day)

*FI* = Fish Intake (kg/day)

*BAF* = BCF

*IF* = Inorganic Proportion Factor (%)
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