Overview

- Assessing Human Health Risk from Chemicals in Environment
- National Primary Drinking Water Regulations
- Assessing Cancer Risks of Drinking Water Disinfection By-product Exposures
- Drinking Water Risk Management Practices and Avoidance of Unintended Consequences
  - Public utilities
  - In home treatment
Problem Formulation
Define the following:
• decision being informed
• assessment goals
• scope
• endpoints
• data needs
Risk Assessment Paradigm

**Hazard identification:**
- Identifies the type and nature of adverse health effects
- Properties of agents having potential to cause adverse health effects

**Exposure assessment:**
- Predicts concentration or amount of a particular agent that reaches a target population
- Environmental releases and fate

**Dose-response assessment:**
- Characterizes human responses to specific concentrations or doses of an agent

**Risk characterization:**
- Predicts the probability of an adverse effect to a human population by a toxic substance

Source: NAS 1983
WHY? Undertake risk assessments to determine if intervention is needed and identify points where intervention could reduce health risks.

Typical environmental and occupational interventions target release (e.g., regulations on levels in drinking water) or human contact with hazardous compounds (e.g., respirators).
Risk assessments rely on information from basic and applied sciences. Risk assessments can inform key research needs.
Human Health Risk Assessment: Research and Decision Contexts

**Research**
- Epidemiology
- Toxicology
- Exposure Sciences
- Environmental Sciences
- Cell Biology
- Biochemistry
- Biomathematics
- Cell Biology
- Biochemistry

**Talk Goal:** Illustrate evaluation of cancer research for an EPA Rulemaking that reduced exposures to some drinking water disinfection byproducts considered carcinogenic.
The level of a contaminant in drinking water at which no known or anticipated adverse effects on the health of person occur and which allows an adequate margin of safety. MCLGs are non-enforceable.

The MCLG is not a legal limit set for Public Water Systems. It is based solely on human health. For known cancer-causing contaminants the MCLG is set at zero. This is because any chemical exposure could present a cancer risk.

The highest level of a contaminant that is allowed in drinking water. MCLs are set as close to MCLGs as is feasible using the best available treatment technology and taking cost into consideration. MCLs are enforceable standards.
EPA must demonstrate that a reasonable opportunity exists to reduce risk

- Prevent Adverse Health Effects with Adequate Margin for Safety: Drinking water concentration including relative source contribution

- Occurrence / Exposure: Is it known to occur at concentrations potentially leading to exposure rates above the reference dose?

- Methods: Is there a reliable analytical method that is economically and technically feasible to measure the contaminant at the reference dose concentration.

- Treatment: Can it be removed cost-effectively with the identified Best Available Technology?

When the benefits of a new MCL does not justify the costs, EPA may adjust the MCL to a level that “maximizes health risk reduction benefits at a cost that is justified by the benefits”.

The 1996 amendments to the Safe Drinking Water Act require that EPA consider a detailed risk and cost assessment, and best available peer-reviewed science, when developing standards.

Goal: protect public health by limiting contaminant concentrations in drinking water

Legally enforceable primary standards & treatment techniques

Apply to public water systems

4 categories of MCLs include carcinogens

- Organic Chemicals (e.g., benzene, PAHs, PCBs, tetrachloroethylene)
- Inorganic Chemicals (arsenic and asbestos)
- Radionuclides (alpha and beta particles, radium 226 & 228, uranium)
- Drinking Water Disinfection By-Products

Source: https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations Accessed 7-22-20
NPDWR: Disinfectant By-Products (DBPs)

Disinfectant + Precursors → DBPs

Treated drinking waters include mixtures of hundreds DBPs

<table>
<thead>
<tr>
<th>Name</th>
<th>MCL (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bromate</td>
<td>0.01</td>
</tr>
<tr>
<td>Haloacetic acids (HAA5)</td>
<td>0.06</td>
</tr>
<tr>
<td>Total Trihalomethanes (TTHMs)</td>
<td>0.08</td>
</tr>
</tbody>
</table>

List carcinogenicity among potential health effects from Long-Term Exposure Above MCL Stage 1 and Stage 2 Drinking Water Disinfection By-Product Rules

https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations#Byproducts

Accessed 7-22-20
Drinking Water Disinfection Risk-Risk Trade-Off

• ‘Risk-risk tradeoffs’ occur when risk management practices implemented to reduce one risk to human health affect another risk (Graham and Wiener 1995)

• Oxidizing agents (e.g., chlorine) added to drinking water to inactivate pathogenic microorganisms by damaging cell membranes, or viral envelopes and capsids. Once weakened, chlorine enters cell/virus, disrupts respiration and genetic activities.

• Oxidizing agents interact with organic and inorganic materials in water forming mixtures of DBPs. Some DBPs in mixtures may increase cancer risk and other health risks.
Assessing Cancer Risk at EPA

Qualitative Assessment of Risk
- Weight-of-Evidence Narrative
- Weight-of-Evidence Descriptors

Quantitative Estimates of Risk
- Dose-Response Assessment
  - Oral Slope Factor = Cancer risk ÷ Dose
  - Inhalation Unit Risk = Cancer risk ÷ Concentration
- Risk Characterization Component
  - Concentration in air or water for “target” risk level
  - For example, 1 person in 1,000,000 (10^-6)
Stage 2 DBP Rule (EPA, 2003)

- Objectives included reducing potential cancer risks associated with DBPs by reducing their peak and average levels in drinking waters

- MCLs: total trihalomethanes (TTHM4—a sum of chloroform, bromodichloromethane, dibromochloromethane, and bromoform) and 5 haloacetic acids (HAA5—a sum of mono-, di-, and trichloroacetic acids and mono- and dibromoacetic acids)

- EPA’s assessment of epidemiology and toxicology cancer studies published (after Stage 1 DBPR was promulgated in 1998) concluded that additional cancer data strengthened evidence of an association of chlorinated water use with bladder cancer, suggest an association with colon and rectal cancers.

- Warranted regulatory action (i.e., MCLs) beyond Stage 1 DBPR

https://www.govinfo.gov/content/pkg/FR-2003-08-18/pdf/03-18149.pdf
Multiple epidemiology studies have investigated the relationship between exposure to chlorinated surface water via drinking water and cancer.

As examples, 2 studies (Yang et al. 1998 and Koivusalo et al. 1998) reported associations of DBP exposures with bladder cancer.

- Yang: report a positive association between consumption of chlorinated drinking water and bladder cancer.
- Koivusalo reported increased risk as a function of increasing DBP exposure duration. Long exposure durations (≥45 years) associated with ~ 2-fold increase in bladder cancer risk.

Lab animal studies reported increased tumor incidences at several sites in BDCM exposed rats and mice (NTP 1987); colon tumors in bromoform exposed rats (NTP 1989); development of preneoplastic lesions of colon cancer, in animals exposed to DBP mixtures (DeAngelo et al. 2002)

Carcinogenicity and cancer potency studies inform the weight of evidence, quantitative risk estimate, and MCL.
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  ➢ Public utilities
  ➢ In home treatment
Disinfection Byproduct Control

One can control or avoid DBPs a number of different ways

• Remove the precursors (natural organic matter) to DBP prior to disinfection
  ➢ Granular Activated Carbon: Cincinnati (Miller plant), Northern Kentucky Water District, Clermont County (Harsha Lake)
  ➢ Enhanced coagulation: Akron
  ➢ Softening: Cincinnati (Bolton plant), Columbus, Dayton
  ➢ Riverbank filtration: Cincinnati (Bolton plant), Louisville, Clermont County

• Use a final disinfectant that produces fewer regulated disinfection byproducts
  ➢ Louisville

• Remove disinfection byproducts after formation
  ➢ Aeration in high water tanks (rare)
  ➢ Point of entry (POE) or Point of use (POU): GAC or high pressure (reverse osmosis) membranes (homeowner’s choice)

• Bottled water
  ➢ Flint, MI (was used as a temporary mechanism)
Per- and Polyfluoroalkyl Substances (PFAS)

A class of chemicals
- Chains of carbon (C) atoms surrounded by fluorine (F) atoms
  - Stable C-F bond
- Some PFAS include oxygen, hydrogen, sulfur and/or nitrogen atoms, creating a polar end

Perfluorooctanoic acid (PFOA)
Perfluorooctanesulfonic acid (PFOS)
Ineffective Treatments
Conventional Treatment
Low Pressure Membranes
Biological Treatment (including slow sand filtration)
Disinfection
Oxidation
Advanced oxidation

Effective Treatments

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Percent Removal</th>
<th>Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anion Exchange Resin (IEX)</td>
<td>90 to 99</td>
<td>Effective</td>
</tr>
<tr>
<td>High Pressure Membranes</td>
<td>93 to 99</td>
<td>Effective</td>
</tr>
<tr>
<td>Powdered Activated Carbon (PAC)</td>
<td>10 to 97</td>
<td>Effective for only select applications</td>
</tr>
<tr>
<td>Granular Activated Carbon (GAC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extended Run Time</td>
<td>0 to 26</td>
<td>Ineffective</td>
</tr>
<tr>
<td>Designed for PFAS Removal</td>
<td>&gt; 89 to &gt; 98</td>
<td>Effective</td>
</tr>
<tr>
<td>Treatment</td>
<td>Advantages</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------------------------------------------------------------------------</td>
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</tbody>
</table>
| Granular Activated Carbon (GAC) | Most studied technology  
Will remove 100% of the contaminants, for a time  
Good capacity for some PFAS  
Will remove a significant number of disinfection byproduct precursors  
Will help with maintaining disinfectant residuals  
Will remove many co-contaminants  
 Likely positive impact on corrosion (lead, copper, iron) |
| Anion Exchange Resin (PFAS selective) | Will remove 100% of the contaminants, for a time  
High capacity for some PFAS  
Smaller beds compared to GAC  
Can remove select co-contaminants |
| High Pressure Membranes       | High PFAS rejection  
Will remove many co-contaminants  
Will remove a significant number of disinfection byproduct precursors  
Will help with maintaining disinfectant residuals |
<table>
<thead>
<tr>
<th>Process Type</th>
<th>Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Granular Activated Carbon (GAC)</strong></td>
<td>GAC run time for short-chained PFAS (shorter run time)</td>
</tr>
<tr>
<td></td>
<td>Potential overshoot of poor adsorbing PFAS if not designed correctly</td>
</tr>
<tr>
<td></td>
<td>Reactivation/removal frequency</td>
</tr>
<tr>
<td></td>
<td>Disposal or reactivation of spent carbon</td>
</tr>
<tr>
<td></td>
<td>Releases from reactivation facilities</td>
</tr>
<tr>
<td><strong>Anion Exchange Resin (PFAS selective)</strong></td>
<td>Run time for select PFAS (shorter run time)</td>
</tr>
<tr>
<td></td>
<td>Overshoot of poor adsorbing PFAS if not designed correctly</td>
</tr>
<tr>
<td></td>
<td>Unclear secondary benefits</td>
</tr>
<tr>
<td></td>
<td>Disposal of resin and potential releases</td>
</tr>
<tr>
<td><strong>High Pressure Membranes</strong></td>
<td>Capital and operations costs</td>
</tr>
<tr>
<td></td>
<td>Membrane fouling</td>
</tr>
<tr>
<td></td>
<td>Corrosion control</td>
</tr>
<tr>
<td></td>
<td>Lack of options for concentrate stream treatment or disposal</td>
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</table>
Is treatment cost effective?

How does EPA identify the appropriate treatment technology

For small systems, EPA identifies compliance technologies as affordable when annualized cost of treatment is lower than 2.5% of median household income minus average annual baseline household water utility costs.*

Notes:
1) EPA does not regulate private well water
2) FDA regulates bottled water, not EPA

GAC Treatment Cost: PFOA, TCE, 1,1 DCA

EPA will be evaluating additional water qualities and designs

- Full Scale
- 26 min EBCT
- Lead-Lag configuration
- F600 Calgon carbon
- 1.5 m³/min flow
- Full automation
- POTW residual discharge
- Off site regeneration
- 135,000, 70,000, and 11,000 bed volumes to breakthrough for TCE, PFOA, and 11DCA, respectively.

Weaker adsorbing compounds have higher costs

GAC can cost-effectively remove PFOA/PFOS

Average Flow (MGD)

Total Cost ($/1000 gallons treated)
Decision on Home Treatment

• A very small community (i.e., less than 200 households) may choose Point-of-Use (POU) treatment over centralized treatment
  ➢ State dependent
  ➢ Very rare

• Households with private wells may be supplied with home Point-of-Entry (POE) systems (e.g., due to litigation)

• A homeowner may make a personal choice to install POU or POE treatment

• Bottled water is an unsustainable long-term approach (cost and otherwise)
For utilities/homeowners that have contaminants in their source water at concentrations of health concern

1) Eliminate source of the contaminant to the source water
2) Either choose a new source of water or choose a technology, design, and operational scheme that will reduce contaminant to safe levels at the lowest possible cost in a robust, reliable, and sustainable manner that avoids unintended consequences

Issues to address (not inclusive)

1) Capital and operating costs are affordable
2) Staff/homeowner can handle operational scheme over the long term
3) Technology can operate long term under a reasonable maintenance program
4) Technology and treatment train can handle source water quality changes
5) Any waste stream generated can be treated or disposed in a sustainable and cost-effective manner over the long term
Choice of technology, design, and operations can lead to...

1) Negative impacts on the performance of the rest of the treatment system for other parameters (e.g., decreased control of particulates/pathogens, taste & odor compounds, other source water contaminants)

2) Negative impacts on the distribution system and/or premise plumbing (e.g., increased lead, copper, or iron corrosion; disinfection residual maintenance difficulties)

EPA is conducting research on optimizing drinking water treatment for contaminants of concern
To Achieve other Positive Benefits

Choice of technology, design, and operation can have...

1) Positive impacts on the performance of the rest of the treatment system for other parameters (e.g., improved control of particulates/pathogens, taste & odor compounds, industrial contaminants, pesticides, pharmaceuticals, personal care products, endocrine disruptors)

2) Positive impacts on the distribution system and/or premise plumbing (e.g., decreased lead, copper, or iron corrosion; better disinfection residual maintenance; fewer disinfection byproducts)

Improved Treatment
Improved Disinfection
Decreased Corrosion

EPA is a resource for communities, states, and regions
Trade-offs in both setting and implementing standards

Balance Risks
- Route of exposure (relative source contribution)
- Risk Risk Trade-Offs
  - Pathogen reduction and introduction of DBPs
    - Analyses improve with understanding of health risks associated with chemical and pathogen exposures
  - Chemical Removal and potential reduction in secondary benefits
  - Water – Air Tradeoffs
    - Disinfection requires electricity and chemicals. Generating electric emits some carcinogenic pollutants to atmosphere.

Balance Treatment Efficacy with
- Ability to sustain operations (costs, operator expertise, management capability)
- Ability to manage/dispose of wastes (e.g., spent media, waste streams)
- Unintended consequences
  - Negative impact on downstream treatment systems
  - Loss of disinfectant residual (e.g., Legionella regrowth)
  - Increased corrosion (e.g., lead)
  - Lack of monitoring (e.g., POU)

EPA’s drinking water goals include identifying, monitoring, and characterizing health risks posed by chemical carcinogens in drinking waters to inform the trade-offs.
Disclaimer

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Questions?

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