

Minnesota's Proposed Approach for Addressing Children's Risks in Setting Drinking Water Criteria

**NE SRA Regional Chapter
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Outline

- Regulatory Background
- Groundwater Rule Revision Effort
 - Initiation of Rule Revision
 - Re-evaluation of algorithm inputs
 - 2004/5 Draft Recommendations
 - External Expert Panel Review
 - 2007 Revised Recommendations
- Groundwater Rule revision status
- Future Activities

Background

What Is A Health Risk Limit?

A Health Risk Limit (HRL) is the concentration of a groundwater contaminant, or mixture of contaminants, that can be safely consumed daily for up to lifetime.

1993/94 Promulgated ~ 130+ chemicals

Background

Minnesota Legal Requirements

Ground Water Protection Act of 1989 (Mn. Stat., Ch. 103H)

- Goal: “. . . groundwater be maintained in its natural condition, free from any degradation caused by human activity.”
- Authorized development of HRLs for situations in which degradation has occurred

Background

New Legal Requirements

- Drinking water or air quality standards established or revised by the commissioner of health must:
 - Be based on scientifically acceptable, peer-reviewed information; and
 - Include a reasonable margin of safety to adequately protect the health of infants, children, and adults . . .”

(Health Standards Statute of 2001, Minnesota Statute 144.075)

Groundwater Rule Revision Announced – late 2001

- Statutory mandate to periodically review HRLs (last promulgation 1993/94)
- New toxicological data
- Additional contaminants
- New water intake data



Re-evaluate 1993/94 methodology

Groundwater Rule Revision

Reevaluation of Algorithm Inputs

Standard Algorithm in 1993/94

$$\text{Noncancer HRL} = \frac{\text{RfD (mg/kg-day)} \times \text{RSC} \times 1000 \text{ ug/mg}}{(2 \text{ L}/70 \text{ kg-day})}$$

Toxicity

Exposure

$$\text{Cancer HRL} = \frac{(\text{Risk Level, } 1 \times 10^{-5}) \times 1000 \text{ ug/mg}}{\text{Slope Factor (per mg/kg-d)} \times 2 \text{ L}/70 \text{ kg-d}}$$

Groundwater Rule Revision Influential Guidance -

- EPA RfD/RfC Review
 - Review of the Reference Dose and Reference Concentration Process, December 2002
<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55365>

- EPA Cancer Guidelines
 - Supplemental Guidance for Assessing Cancer Susceptibility from Early-life Exposure to Carcinogens, March 2005 <http://cfpub.epa.gov/ncea/>

Groundwater Rule Revision Toxicity Reevaluation - Noncancer

- Differences between children & adults (Intraspecies VF)
 - Absence of data on early life (Database UF)
- Adequate
(given multiplicative approach)
- Basis of RfD for developmental toxicants
- Maternal dose
(May be over- or under-protective)

Groundwater Rule Revision Toxicity Reevaluation - Cancer

- Early Life Evaluations
 - McConnell 1992
 - Ginsberg 2003
 - MDH 2004
 - Hattis et al, 2004 & 2005
 - EPA Supplemental Guidance 2005
 - California EPA 2006
- Less-than-Lifetime Evaluations

Groundwater Rule Revision Exposure Reevaluation

- Evaluate most recent intake data
 - Estimated Per Capita Water Ingestion in the United States (2004 Update Based on 1994-96 and 1998 CSFII)
(<http://epa.gov/waterscience/criteria/drinking/percapita/>)

- Consider timing of exposure
 - Periods of increased sensitivity to toxicity?
 - Periods of increased intake?

- Consider duration of exposure
 - Length of time necessary to produce the adverse effect

Groundwater Rule Revision

Exposure Reevaluation - Noncancer

- Developmental
 - Adverse effects on the developing organism that may result from exposure prior to conception (either parent), during prenatal development, or postnatally until the time of sexual maturation. Exposure duration may be as short as a single dose.
- Chronic
 - Repeated exposure for more than approximately 10% of the lifespan in humans (> 90 days in laboratory rodents)

Groundwater Rule Revision Exposure Reevaluation - Noncancer

Age (years)	Percentile Intake vs 2 L/70kg-day		
	90th	95th	99th
< 0.5	6	8	10
≤ 8 TWA (~10% of a lifetime)	2	3	4
Adults (20+)	1	1	2
Pregnant Women	1	1.5	2
Lactating Women	2	2	2

SOURCE: Estimated Per Capita Water Ingestion and Body Weight in the United States – An Update. (EPA, Oct. 2004) Part IV, Table A2 Community Water Consumer Only, page E-145. <http://www.epa.gov/waterscience/drinking/percapita>

Groundwater Rule Revision 2004 Draft Recommendation

Noncancer Algorithm

$$\text{nHRL}_{\text{develop}} = \frac{\text{RfD (mg/kg/day)} \times \text{RSC (0.2)} \times 1000 \text{ ug/mg}}{(2 \text{ L/70 kg-day}) \times \text{Intake AF (6)}}$$

$$\text{nHRL}_{\text{chronic}} = \frac{\text{RfD (mg/kg/day)} \times \text{RSC (0.2)} \times 1000 \text{ ug/mg}}{(2 \text{ L/70 kg-day}) \times \text{Intake AF (3)}}$$

Groundwater Rule Revision Exposure Reevaluation - Cancer

- Duration of Exposure
 - Short-term Early Life vs. Standard Adult Bioassay
 - Adult Stop-Exposure Studies (Halmes et al, 2000)

Groundwater Rule Revision 2004 Draft Recommendation

Cancer Algorithm:

$$\text{cHRL} = \frac{(\text{Risk Level, } 1 \times 10^{-5}) \times 1000 \text{ ug/mg}}{\text{SF (mg/kg-day}^{-1}\text{) } \times \text{Potency AF (2)} \times (2\text{L}/70 \text{ kg-d)} \times \text{Intake AF (3)}}$$

Groundwater Rule Revision 2004 Draft Recommendation

- Published Draft (December 2004)
 - Presented overall approach
 - HRL values for 82 chemicals
- Received Comments from Public
- External Peer Review (November 2005)

Groundwater Rule Revision Expert Advisory Panel

Charge Question 1 – *Discuss and comment on MDH's decision to utilize a minimum chronic period of 10% of a lifetime (approx. 7 years) to develop HRLs for chronic, non-cancer effects. Do you find it prudent and reasonable? If so, why? If not, what would be a reasonable minimum chronic period of time?*

- Prudent and reasonable
- Recommendations: 1) assess less than chronic durations to ensure protectiveness of shorter durations, and 2) if subchronic-to-chronic UF applied do not use minimal chronic intake adjustment

Groundwater Rule Revision Expert Advisory Panel

Charge Question 5 – *Discuss whether the [potency and exposure] adjustments selected by MDH are prudent and reasonable. Why or why not? If not, what adjustment(s) would you recommend?*

- Proposed adjustments (overall correction ~ 6) are reasonable and prudent
- Recommendations:
 - 1) multiple window approach and
 - 2) provide justification for not using EPA Supplemental Approach

Groundwater Rule Revision Expert Advisory Panel

Charge Question 6 – *Is MDH's decision to adjust the cancer slope factor for mutagens and nonmutagens a prudent and reasonable approach? Why or why not? If not, what approach would you recommend?*

- Panel expressed a range of diverse opinions.

Groundwater Rule Revision 2006 – Reassess 2004 Draft

- Regulatory updates
 - Guidance documents
 - Federal and state activities
- Input on 2004 revision
 - Public Comments
 - Expert Panel Recommendations

Groundwater Rule Revision 2007 Revised Recommendations

- Non-cancer HRLs (nHRLs)
 - Multiple duration RfDs
 - Multiple duration nHRLs

- Cancer HRLs (cHRLs)
 - EPA life-stage cancer potency adjustment as default

Groundwater Rule Revision 2007 Reevaluation - Noncancer

- **Acute** – up to 1 day
- **Short-term** - repeated exposure for > 1 day up to 30 days;
- **Subchronic** - repeated exposure for > 30 days, up to ~ 10% of the life span in humans (> 30 days up to ~ 90 days in typically used laboratory rodent species); and
- **Chronic** - repeated exposure for > ~ 10% of the life span in humans (> ~ 90 days to 2 years in typically used laboratory rodent species).

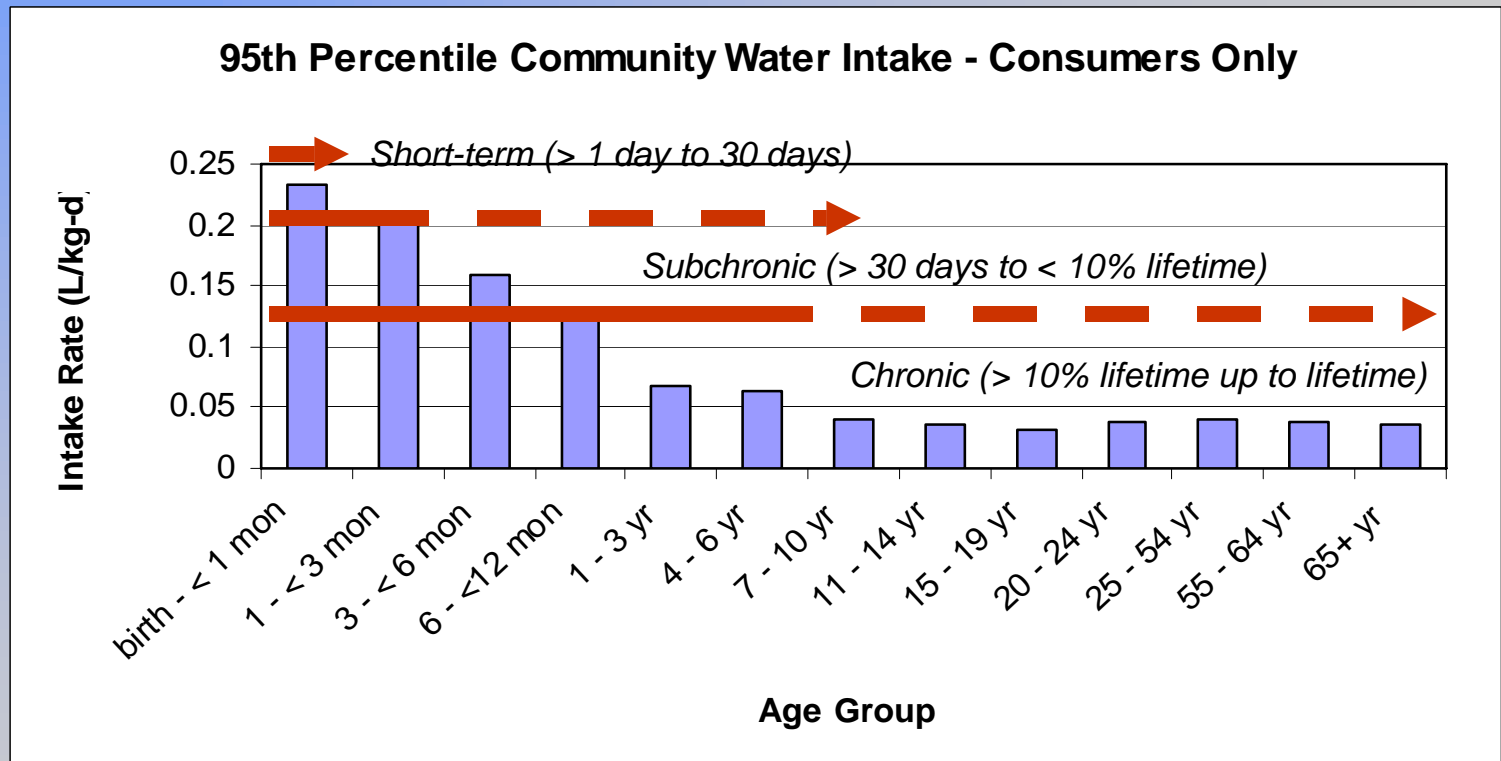
EPA 2002 Review of the Reference Dose and Reference Concentration Process
(<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55365>)

Groundwater Rule Revision 2007 Reevaluation – Noncancer (Toxicity)

Challenges - -

- ✓ Are duration specific assessments available?
- ✓ Is the study of adequate quality?
 - Did study evaluate relevant endpoints? (lack of detailed assessment in less than chronic studies)
 - Was life stage sensitivity for appropriate endpoints evaluated?
- ✓ Are data relevant to timing and duration issues reported
- ✓ No assessment of latency

Groundwater Rule Revision 2007 Reevaluation – Noncancer (Intake)



SOURCE: Estimated Per Capita Water Ingestion and Body Weight in the United States – An Update. (EPA, Oct. 2004) and EPA 2006 Child-Specific Exposure Factors Handbook (External Review Draft)
<http://www.epa.gov/waterscience/drinking/percapita> & <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=56747>

Groundwater Rule Revision 2007 Reevaluation – Noncancer

(default)

$$\text{nHRL}_{\text{short-term}} = \left[\frac{\text{RfD (mg/kg/day)} \times 1000 \text{ ug/mg}}{0.234 \text{ L/kg-d}} \right] \times \text{RSC (0.5 or 0.2)}$$

$$\text{nHRL}_{\text{subchronic}} = \left[\frac{\text{RfD (mg/kg/day)} \times 1000 \text{ ug/mg}}{0.076 \text{ L/kg-d}} \right] \times \text{RSC (0.2)}$$

$$\text{nHRL}_{\text{chronic}} = \left[\frac{\text{RfD (mg/kg/day)} \times 1000 \text{ ug/mg}}{0.039 \text{ L/kg-d}} \right] \times \text{RSC (0.2)}$$

Groundwater Rule Revision 2007 Reevaluation - Noncancer

- Potentially 3 duration specific HRLs may be derived (e.g., short-term, subchronic, & chronic)
- Shorter term HRLs may not be protective of longer durations (e.g., $HRL_{\text{short-term}} > HRL_{\text{subchronic}} > HRL_{\text{chronic}}$)
- Longer term HRLs must be protective of shorter durations (e.g., $HRL_{\text{chronic}} \leq HRL_{\text{subchronic}} \leq HRL_{\text{short-term}}$)

Groundwater Rule Revision 2007 Reevaluation - Cancer

Adopt EPA Supplemental Guidance Approach:

Cancer HRL =

$$\frac{\text{(Additional Lifetime Cancer Risk, } 1 \times 10^{-5}) \times \text{(Conversion Factor, } 1000 \text{ ug/mg)}}{[(\text{SF} \times 10 \times 0.137 \text{ L/kg-d} \times 2) + (\text{SF} \times 3 \times 0.046 \text{ L/kg-d} \times 13) + (\text{SF} \times 1 \times 0.039 \text{ L/kg-d} \times 55)/70]}$$

**Not limited to chemicals with mutagenic MOA.
Applied to linear dose-response carcinogens.**

Groundwater Rule revision status

- Initiated reevaluation of chemicals using 2007 recommended approach
- Completing a revised draft Rule and SONAR (July, 2007)
 - Post for stakeholder review and conduct internal review
- Publish Proposed Rule (Nov – Dec,2007)
 - Official 30 Day Comment Period
 - Information Session(s) and receipt of comments
- Administrative law judge reviews the proposed rule
- Rule is promulgated

Future Activities –

- Additional HRL chemicals (> 200)
- Legislative mandate to adjust for age-related differences in toxicity or exposure applies to air as well as water standards

HRL Rule Revision Contacts and Web Page

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<http://www.health.state.mn.us/divs/eh/groundwater/hrlgw/index.html> (Subscribe to GovDelivery service)