# **Health Consultation**

SWEET AREA FLUORIDE

Evaluation of Fluoride in Private Drinking Water Wells in the Communities of Sweet, Montour and Surrounding Areas

GEM COUNTY, IDAHO

September 9, 2009

Prepared by

The Idaho Division of Public Health Bureau of Community and Environmental Health and The Agency for Toxic Substances and Disease Registry Division of Regional Operations

# Foreword

The State of Idaho, Idaho Division of Public Health (IDPH), Bureau of Community and Environmental Health (BCEH) jointly prepared this public health consultation with the Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR is part of the U.S. Department of Health and Human Services and is the principal federal public health agency responsible for health issues related to environmental contaminants. This health consultation was prepared in accordance with methodologies and guidelines developed by ATSDR.

The health consultation is an approach used by ATSDR and IDPH to respond to requests from concerned residents for health information on hazardous substances in the environment. The health consultation process evaluates sampling data, determines whether exposures have occurred or could occur, reports any potential harmful effects, and recommends actions to protect public health.

# SUMMARY

	BCEH's top priority is to ensure that the Sweet Community has good information to safeguard its health. Southwest District Health Department (SWDHD) asked BCEH to conduct this health consultation. The purpose of the consultation is to evaluate the public health risk of drinking private well water that is high in fluoride and eating food made with this water.			
INTRODUCTION				
CONCLUSION	BCEH concludes that fluoride in drinking water from the 6 wells evaluated in this health consultation <i>could harm the health of</i> <i>children and adults</i> who drink the water and/or eat food made with the water if consumed on a daily basis for longer than a year. This is a public health hazard.			
BASIS FOR DECISION	In children, chronic exposure will likely stain and/or cause pitting of teeth. In adults, chronic exposure may contribute to increased rate of bone fractures.			
NEXT STEPS	<ul> <li>BCEH will work with SWDHD to contact the owners of the wells with high fluoride levels and advise them of the following: <ul> <li>the possible health risks of drinking their well water</li> <li>the need to drink treated water, bottled water, or water that meets federal drinking water standards</li> <li>to prepare all foods (including infant formula) using treated water, bottled water, or water that meets federal standards</li> <li>the need to talk to their heath care provider if they continue to drink the untreated water at home</li> <li>the fact that heating or boiling the water does not reduce the amount of fluoride</li> </ul> </li> </ul>			
	BCEH will work with SWDHD to raise awareness of the issue of high fluoride levels in private wells in Gem County by attending Gem County Commissioner's open forums. BCEH will present information on the possible health impacts of fluoride in private wells and well testing for fluoride.			

# FOR MORE INFORMATION

If you have concerns about fluoride in your well water, you should contact Dr. Kai Elgethun at 208-334-5682. You may also call ATSDR at 1-800-CDC-INFO and ask for information on the Sweet Community site.

# **Purpose and Statement of Issues**

Naturally-occurring fluoride in private wells is a problem in many parts of Southwest Idaho. Fluoride has beneficial effects, but at higher concentrations, fluoride is toxic.

In January 2009, the Bureau of Community & Environmental Health (BCEH) was contacted by Southwest District Health Department (SWDHD), a local health agency, regarding high fluoride levels in several private wells near Sweet, Idaho. These and other wells have tested high for fluoride for many years due to a naturally-occurring source of the element in the area. Fluoride levels in these wells have increased slightly over the past few years. Fluoride levels at the Sweet-Montour community school have been very high in the past 15 years (16-18 mg/L), and the school currently has a treatment system installed to bring levels below the Maximum Contaminant Level (MCL). The Environmental Protection Agency (EPA) sets water MCLs that are protective of human health. The MCL for fluoride is 4 mg/L (milligrams per liter).

Evidence suggests that human cancers are not associated with exposure to naturallyoccurring fluoride in water (ATSDR, 2003). However, natural fluoride can cause other adverse health effects in people. Fluoride has beneficial effects up to certain low threshold levels. At higher concentrations, fluoride is toxic. The most common systemic effects of fluoride toxicity are bone and teeth defects. At sufficient exposure duration and dose, irreversible skeletal fluorosis can occur, causing painful irritation of bone and joints.

While most exposure to fluoride in the Sweet area is from drinking water, there is also the possibility that home-grown produce exposed to water containing fluoride could concentrate the fluoride. People could then be exposed to additional fluoride if they eat the produce. Fluoride has an affinity for bone and teeth (and egg shells); however, it is not expected to be in edible meat or egg yokes or whites from animals raised with high fluoride water. Fruits also are not expected to concentrate fluoride. Vegetables have widely varying fluoride uptake and fluoride concentration in edible tissues: some concentrate fluoride, a portion of it never enters the blood and is excreted from the body in the feces within a few days. Much of the portion of fluoride that does enter the blood leaves the body through the urine within a few days. Still, a small amount can stay in the teeth, bones, and kidneys and may stay there for years.

# **EPA Drinking Water Standards**

EPA is responsible for setting the MCLs. The MCL is the highest level of a chemical that is permitted in public drinking water systems. MCLs are set as close to Maximum Contaminant Level Goals (MCLGs) as feasible using the best available treatment technology and taking cost into consideration. MCLGs are the level of a contaminant in drinking water below which there is no known or expected risk to health. MCLGs allow for a margin of safety and are non-enforceable public health goals while MCLs are enforceable standards (EPA, 2009). The MCLG for fluoride in drinking water is 4 mg/L, since some level of fluoride is effective at preventing tooth decay. The MCLG is based

on the health endpoint of teeth discoloration in children and assumes a chronic exposure duration. The MCLG for fluoride is the same as the MCL of 4 mg/L. There is considerable debate about whether the MCLG and MCL are protective enough, since there is evidence of tooth discoloration in children exposed to slightly less than 4 mg/L of fluoride in water. This debate also continues because the lowest observable adverse effect level (LOAEL) for the health endpoint of increased rate of bone fractures in persons age 50 years and older can occur with ingestion of a concentration just slightly higher than the MCL/MCLG.

Private well owners are not required to test their water or to comply with MCLs, but health officials strongly encourage voluntary compliance. Wells that serve schools (and no other connections) are also exempt from most MCLs, including fluoride, because they are considered "transient systems".

#### Background

In general terms, the compounds we call fluoride are the element fluorine plus sodium or calcium. When dissolved in water, what is being measured is the element fluorine dissolved in an aqueous solution. Since the fluoride MCL of 4 mg/L was established in 1986, the drinking water from a number of Sweet area wells has consistently exceeded that level. Heating or boiling water does not remove fluoride. Reverse osmosis and distillation treatment systems can be installed to lower high fluoride levels to below the MCL and are certified for this purpose (NSF Standards 53, 58, 62; 2009).

# **Site Description**

The approximate location of this area is shown in Figure 1. Figure 2 shows the location of the Sweet-Montour school in relation to the surrounding rural areas.



Figure 1: Map of Idaho showing location of Sweet and surrounding areas in Gem County.



Figure 2: Topographic map of the Sweet area showing the location of the Sweet-Montour School (circled in blue). The school currently has point-of-use treatment for fluoride but many homes and businesses do not.

# **Source of Contamination**

Fluoride is a natural and commonly-occurring compound that is a crystalline ionic salt containing the halogen element fluorine. Rocks, soil, surface and underground water, air, plants, and animals all contain varying amounts of fluoride. Fluoride in water comes from different sources; the majority comes from the erosion of natural deposits by water.

# Sampling

Some private well samples were collected by Southwest District Health Department or private well owners in accordance with Idaho Bureau of Labs (IBL) protocol for water systems in Idaho. Other private well samples were collected by the United States Geological Survey (USGS) in accordance with USGS protocol. Private well samples were collected between 2003 and 2009. Samples at the Sweet-Montour school were collected by the Idaho Department of Environmental Quality (IDEQ) beginning in 1995.

# Analysis

Water samples were received by IBL and various contract labs. Samples were analyzed for total fluoride using EPA methods 340.1, 340.2 or 340.3 (EPA, 1998).

# Results

Reference values and values used in calculations are shown in Appendix A. Fluoride concentrations for private wells and for the Sweet-Montour School are shown in Table 1. Fluoride ingestion dose estimates are shown in Table 2.

Type of Well	Fluoride (mg/L)	Collection Date
Private Residential	12.4	1/6/2003
Private Residential	9.6	6/22/2005
Private Residential	11.4	7/27/2006
Public School	18.4	10/19/2007
Private Residential	20.0	9/16/2008
Private Residential	17.3	1/9/2009
	MEAN 14.9	

Table 1: Fluoride concentrations >4 mg/L in the Sweet area, 2003-2009

Table 2: Fluoride ingestion dose estimates

Individual	Dose based on mean	Dose based on maximum
	(mg/kg/day)	(mg/kg/day)
Adult	0.42	0.57
Child*	1.04	1.40
Infant	2.12	2.84

\*includes incidental water ingestion estimate of 50 mL/day

All estimated doses exceed the ATSDR Chronic Minimal Risk Level (MRL) of 0.05 milligram per kilogram of body weight per day (mg/kg/day).

# **Route of Exposure**

Ingestion appears to be the only feasible route of significant exposure to fluoride in the Sweet area. This exposure is primarily through drinking water; however, eating plants irrigated by the water may contribute to exposure. Exposure through the skin or through breathing, such as would occur while showering, are addressed in this document as well. Since it is known that there is fluoride in well water and that residents use the water for drinking and for garden irrigation, a completed pathway for exposure exists. In other words, it is known that people who use private wells in the Sweet area are being exposed to fluoride.

# Discussion

# Ingestion

ATSDR uses comparison values called Minimal Risk Levels (MRLs) to screen contaminants to determine if there may be possible health issues from exposures. An MRL is defined as an estimate of daily human exposure to a substance that is likely to be without appreciable adverse health effects. ATSDR has three kinds of MRLs that are defined very precisely: acute MRLs are based on 1-14 days of exposure, intermediate MRLs are based on 15-364 days of exposure, and chronic MRLs are based on 365 days and longer exposure. Only a chronic MRL exists for fluoride, at 0.05 mg/kg/day. The health endpoint considered by ATSDR is increased bone fractures in adults age 50 and older. The EPA reference dose (RfD - the EPA's equivalent of ATSDR's MRL) is very similar at 0.06 mg/kg/day, but the health endpoint considered is objectionable tooth staining. The EPA RfD is based on a no observed adverse effect level (NOAEL) of 0.06 mg/kg/day.

Using the standard exposure assumptions for adults which assumes a water ingestion rate of 2 L/day and a body weight of 154 lbs (70 kg), a fluoride concentration that would provide an intake of 0.05 mg/kg/day for an adult can be calculated. This concentration is 1.75 mg/L. For a child weighing 33 lbs (15 kg) and ingesting 1 L/day, the concentration providing the MRL is 0.75 mg/L. For an infant weighing 10 lbs (4.5 kg) and ingesting 0.64 L/day, this concentration is 0.35 mg/L.

In contrast, the EPA MCL for drinking water is 4 mg/L which is much higher than any of the values corresponding to the ATSDR chronic MRL for adults, children, and infants. The MCL is in fact set at a level above the NOAEL but below the lowest observed adverse effect level (LOAEL) (using a 2.5 safety factor applied to the LOAEL).

It is possible that in some sensitive human populations, tooth appearance could be altered by doses of fluoride above the MRL, and certainly by doses of fluoride at the MCL. It is also possible that rates of bone fracture could be elevated in individuals age 50 or older if they have consumed a lifetime of fluoride in water at levels slightly above the MCL.

# Incidental Water Ingestion, Bathing or Swimming

Since many wells containing high levels of fluoride in the Sweet area are geothermal (at temperatures ranging from slightly above ambient to very hot), they are commonly used for bathing and/or swimming. Thus, incidental ingestion by children should be considered as an exposure pathway. Incidental ingestion by adults and infants was not considered due to different behavior patterns (adult are assumed to avoid swallowing bathing water and infants are assumed to be monitored by an adult). See Appendix C for calculations. It was assumed (using the EPA Child Specific Exposure Factors Handbook) that 50 mL (about 10 teaspoons) of water per daily bathing event might be ingested by a child (EPA, 2008). This exposure might contribute 0.067 mg/kg/day, or about 1/20<sup>th</sup> of the daily drinking water dose. While not negligible, this is a small amount.

# Plant Uptake: Fruits and Vegetables

Some residents may raise fruits and vegetables using the water from high fluoride wells and have concerns about the fluoride being taken up by plants and stored in the parts that are eaten. To evaluate the possible uptake of fluoride in fruits and vegetables grown using water with elevated levels of fluoride, a literature review was conducted. The literature review found studies of fluoride uptake in plants by Khandare and Rao (2006) and Miller et al. (1999). In these studies, test gardens were planted and the fluoride uptake and concentration in different types of vegetables were tested.

The Khandare and Rao study found that spinach had a much higher uptake than cabbage, okra, or tomatoes. This is in keeping with other studies which show that typically the leafy green vegetables uptake more compounds than do fruits and other vegetable crops. To determine if eating garden vegetables might contribute appreciably to the total fluoride exposure, calculations were performed using the concentration factor for spinach and the highest detected fluoride concentration of 20.0 mg/L. The annual consumption rate for spinach was derived from values in the EPA Exposure Factors Handbook (1997). After performing the calculations, it was determined that even under worst-case situations, the contribution of fluoride from spinach is negligible. See Appendix D for calculations and notes.

#### Dermal

Dermal dose-response data are limited to rat studies. Preparations of 0.5% and 1% fluoride were tested on rats. This equates to 5,000 and 10,000 parts per million (ppm). At these levels, necrosis, edema, and damage to skin mast cells were observed with more severe damage at the higher concentration. The level in water from the highest well is approximately 20.0 ppm, or about 250 times lower than 5,000 ppm. It is unlikely that skin damage would occur at 20.0 ppm. Soluble fluoride is somewhat absorbed through the skin, though ATSDR and EPA do not reference any studies that quantify the amount and rate of absorption.

# Inhalation

In general terms, fluoride is the element fluorine plus sodium or calcium. It is possible for people to inhale this soluble fluoride in water vapor when showering, though it does not behave like fluorine gas. Inhalation data on fluorine come from studies of fluorine gas. Lacking data on how fluoride inhalation into the lungs might compare to fluorine gas inhalation, it is not possible to calculate an exposure and resulting risk. However, it is not believed that the inhalable concentration of fluoride present in water droplets and vapor during showering poses a risk to health.

# **Child Health Considerations**

In communities where there are concerns regarding exposures to hazardous chemicals, the many physical differences between children and adults demand special emphasis. In this study, children are the main focus of our concern. Children drinking this water are at greater risk than adults from exposure to fluoride in water. A child's lower body weight and higher intake rate per unit body weight results in a greater dose of fluoride per unit of body weight. Also, staining and pitting of teeth occur during developmental years of childhood. The levels of fluoride in these wells are high enough to be considered a public health hazard for all young children who weigh 15 kg (33 pounds) or less.

# Conclusions

- 1. BCEH concludes that fluoride in drinking water from the 6 wells evaluated in this health consultation *could harm the health of children* who drink the water and/or eat food made with the water if consumed on a daily basis for longer than a year. It will likely stain and/or cause pitting of teeth. This is a public health hazard.
- 2. BCEH concludes that fluoride in drinking water from the 6 wells evaluated in this health consultation *could harm the health of adults* who drink the water and/or eat food made with the water if consumed on a daily basis for longer than a year. It may possibly contribute to increased rate of bone fractures. This is a public health hazard.
- 3. There is no reason to believe that washing clothes or household cleaning with the water poses a health risk. Incidental swallowing of water from swimming and/or bathing might contribute a small amount of exposure to some children.
- 4. Fluoride levels in crops and home-grown produce irrigated with the water is expected to be negligible.

# Recommendations

- 1. Children, particularly younger children, should not drink the tap water from the wells unless it has been properly treated using reverse osmosis. A treatment system is now installed at the Sweet-Montour School. If treatment is not possible in households, then children should be given bottled water or provided water from a source that meets federal drinking water standards.
- 2. Children should not consume food prepared using the tap water from the wells unless it has first been treated using a system such as reverse osmosis or distillation or is from a source known to meet federal drinking water standards.
- 3. If you are concerned about you or your children's health, please talk with your health care provider.

# Public Health Advice/Public Health Action Plan

- 1. BCEH will work with Southwest District Health (SWDHD) to contact owners of the wells with fluoride above the MCL and advise them of the following:
  - the possible health risks of drinking their well water
  - the need to give children treated water, bottled water, or water that meets federal drinking water standards
  - the need to prepare all foods (including infant formula) using treated water, bottled water, or water that meets federal standards
  - the need to talk to their heath care provider if they continue to drink the untreated water at home
  - the fact that heating or boiling the water does not reduce the amount of fluoride
  - water treatment systems they can install to reduce the level of fluoride
- 2. BCEH will work with SWDHD to raise awareness of the issue of fluoride in private wells in Gem County by attending Gem County Commissioner's open forums to present information on the possible health impacts of fluoride in private wells.
- 3. BCEH will work with SWDHD to promote the testing of private wells for fluoride in Gem County.
- 4. All residents will be encouraged to drink water that meets federal standards.
- 5. This health consultation will be available at the Sweet-Montour School library and directly from BCEH.
- 6. Residents are encouraged to contact BCEH with further questions.

#### **Authors of Report**

Kai Elgethun PhD, MPH Public Health Toxicologist Health Assessor Idaho Division of Public Health Bureau of Community and Environmental Health

#### **Reviewers of Report**

Richard Kauffman, MS Senior Regional Representative, Region 10 Division of Regional Operations Agency for Toxic Substances and Disease Registry

Jim Vannoy, MPH Program Manager Idaho Division of Public Health Bureau of Community and Environmental Health

Megan Keating, MS Health Education Specialist Senior Idaho Division of Public Health Bureau of Community and Environmental Health

Kara Stevens Section Manager Idaho Division of Public Health Bureau of Community and Environmental Health

Elke Shaw-Tulloch, MHS Bureau Chief Idaho Division of Public Health Bureau of Community and Environmental Health

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# **Appendix A: Reference Values for Calculations**

Parameter	Value	Units	Comments
Fluoride(s)	4	mg/L	U.S. EPA Maximum
			Contaminant Level
			for Drinking Water
Ingestion Rate—	2	L/day	
Adult			
Ingestion Rate—	1	L/day	
Child			
Ingestion Rate	0.64	L/day	
Infant			
Body WeightAdult	70/154	kg/lbs	
Body WeightChild	15/33	kg/lbs	Approx. 5 years old
Body Weight	4.5/10	kg/lbs	
Infant			
ATSDR Values			
NOAEL	0.15	mg/kg/day	Li et al., 2001
LOAEL	0.25	mg/kg/day	Li et al., 2001
ATSDR Chronic	0.05	mg/kg/day	>365 days of
MRL			exposure
Most sensitive			Increased bone
health outcome			fractures in adults 50
considered			years and older
<b>EPA Values</b>			
NOAEL	0.06	mg/kg/day	Hodge, 1950
RfD	0.06	mg/kg/day	Chronic exposure;
			Based on EPA
			NOAEL
Most sensitive			Objectionable dental
health outcome			fluorosis (tooth
considered			staining) in children

### Appendix B: Drinking Water Ingestion Calculation

Oral Dose = [IR (L/day) \* Conc. (mg/L)] / BW (kg)

Dose Based on Mean of 14.9 mg/L Adult = [2 L/day \* 14.9 mg/L] / 70 kg = 0.42 mg/kg/day Child = [1 L/day \* 14.9 mg/L] / 15 kg = 0.99 mg/kg/day Infant =[0.64 L/day \* 14.9 mg/L] / 4.5 kg = 2.12 mg/kg/day

Dose Based on Maximum of 20.0 mg/L Adult = [2 L/day \* 20.0 mg/L] / 70 kg = 0.57 mg/kg/day Child = [1 L/day \* 20.0 mg/L] / 15 kg = 1.33 mg/kg/day Infant =[0.64 L/day \* 20.0 mg/L] / 4.5 kg = 2.84 mg/kg/day

IR: Ingestion Rate BW: Body Weight

**Appendix C: Incidental Water Ingestion Calculation** Oral Dose = [IR (L/day) \* Conc. (mg/L)] / BW (kg)

*Dose Based on Mean of 14.9 mg/L* Child = [0.05 L/day \* 14.9 mg/L] / 15 kg = 0.050 mg/kg/day

*Dose Based on Maximum of 20.0 mg/L* Child = [0.05 L/day \* 20.0 mg/L] / 15 kg = 0.067 mg/kg/day

#### Appendix D:

#### Notes on Exposure from Leafy Greens

Leafy greens concentrate more fluoride than any other produce. Spinach is the leafy green for which we have concentration data. The fluoride concentration in spinach after a normal growing season using 20.0 mg/L of water would potentially be approximately 3.4 mg/kg *dry weight spinach* (Khandare and Rao 2006). Since spinach is 93.5% water according to these researchers, this equates to 0.24 mg/kg *wet weight spinach*. The EPA Exposure Factors Handbook consumption estimate for spinach is much lower than that for lettuce; however, to compute a worst-case scenario for consumption of fluoride-containing spinach, the lettuce consumption rate was applied here. This is justified by the assumption that some individuals eat raw spinach in place of or in a similar manner to lettuce. Even with this assumption, the contribution to total fluoride dose from spinach is negligible: approximately 0.000064 (6.4 x  $10^{-5}$ ) mg/kg/day for an adult and 0.000059 (5.9 x  $10^{-5}$ ) mg/kg/day for a child.

Note that these calculations do not take into account how much fluoride is already in the soil and available for uptake in addition to what is taken up from the water. Actual fluoride uptake might therefore be higher than these estimates since it is anticipated that soils watered with the Sweet area well water would have appreciable concentrations of fluoride in them. It is possible and likely for fluoride to concentrate at various depths near the soil surface. The rate and efficiency of uptake from soil into vegetables appears to be significantly slower than that directly from water, but it does occur.

# Certification

This health consultation, Sweet Area Fluoride— Evaluation of Fluoride in Private Drinking Water Wells in the Communities of Sweet, Montour and Surrounding Areas, was prepared by the Idaho Division of Public Health (IDPH) under a cooperative agreement with the federal Agency for Toxic Substances and Disease Registry (ATSDR). It was completed in accordance with approved methodologies and procedures existing at the time the health consultation was initiated. Editorial review was completed by the Cooperative Agreement partner.

Audra Henry Technical Project Officer Division of Health Assessment and Consultation Agency for Toxic Substances & Disease Registry

Alan W. Yarbrough Team Lead, DHAC, CAPEB Division of Health Assessment and Consultation Agency for Toxic Substances & Disease Registry

#### **Appendix E: Glossary**

Acute Occurring over a short time.

### Agency for Toxic Substances and Disease Registry (ATSDR)

The principal federal public health agency involved with hazardous waste issues, responsible for preventing or reducing the harmful effects of exposure to hazardous substances on human health and quality of life. ATSDR is part of the U.S. Department of Health and Human Services.

**BCEH** Bureau of Community & Environmental Health.

Carcinogen A substance that causes cancer.

**Chronic** Occurring over a long time (more than 1 year).

**Comparison value (CV)** Calculated concentration of a substance in air, water, food, or soil that is unlikely to cause harmful (adverse) health effects in exposed people. The CV is used as a screening level during the public health assessment process. Substances found in amounts greater than their CVs might be selected for further evaluation in the public health assessment process.

**Contaminant** A substance that is either present in an environment where it does not belong or is present at levels that might cause harmful (adverse) health effects.

**Dose** The amount of a substance to which a person is exposed over some time period. Dose is a measurement of exposure. Dose is often expressed as milligram (amount) per kilogram (a measure of body weight) per day (a measure of time) when people eat or drink contaminated water, food, or soil. In general, the greater the dose, the greater the likelihood of an effect. An "exposure dose" is how much of a substance is encountered in the environment. An "absorbed dose" is the amount of a substance that actually got into the body through the eyes, skin, stomach, intestines, or lungs.

**EPA** The U.S. Environmental Protection Agency.

**Exposure** Contact with a substance by swallowing, breathing, or touching the skin or eyes. Exposure may be short-term [acute], of intermediate duration [intermediate], or long-term [chronic].

**Hazardous substance** Any material that poses a threat to public health and/or the environment. Typical hazardous substances are materials that are toxic, corrosive, ignitable, explosive, or chemically reactive.

**Health Advisory (HA)** Health Advisories (HA's) provide information on contaminants that do not have an MCL but that can cause human health effects and are known or anticipated to occur in drinking water.

**IDEQ** The Idaho Department of Environmental Quality.

**IDHW** The Idaho Department of Health & Welfare.

**Ingestion rate** The amount of an environmental medium which could be ingested typically on a daily basis. Units for ingestion rate are usually liter/day for water, and mg/day for soil.

Lowest Observed Adverse Effect Level (LOAEL)

The lowest tested dose of a substance that has been reported to cause measurable adverse health effects in people or animals.

#### Maximum Contaminant Level (MCL)

Enforceable drinking water quality standard set by U.S. Environmental Protection Agency (EPA).

#### Maximum Contaminant Level Goal (MCLG)

Non-enforceable drinking water quality standard, used to determine the MCL.

**Media** Soil, water, air, plants, animals, or any other part of the environment that can contain contaminants.

#### No Observed Adverse Effect Level (NOAEL)

The highest tested dose of a substance that has been reported to have no measurable adverse health effects on people or animals.

**Oral Reference Dose (RfD)** An amount of chemical ingested into the body (i.e., dose) below which health effects are not expected. RfDs are published by EPA.

**Organic** Compounds composed of carbon, including materials such as solvents, oils, and pesticides which are not easily dissolved in water.

**Route of exposure** The way people come into contact with a hazardous substance. Three routes of exposure are breathing [inhalation], eating or drinking [ingestion], or contact with the skin [dermal contact].

**Safety factor** A number that is used to account for uncertainty in the data and/or severity of the health effect when calculating an oral RfD or other level or dose to which humans can safely be exposed. Safety factors generally range from 1-100.