



# Public Health Assessment for

**COMMERCE STREET PLUME**

**WILLISTON, CHITTENDEN COUNTY, VERMONT**

**EPA FACILITY ID: VTD098352545**

**APRIL 15, 2014**

For Public Comment

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE**

Agency for Toxic Substances and Disease Registry

**Comment Period Ends:**

**MAY 29, 2014**

THE ATSDR PUBLIC HEALTH ASSESSMENT: A NOTE OF EXPLANATION

This Public Health Assessment-Public Comment Release was prepared by ATSDR pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) section 104 (i)(6) (42 U.S.C. 9604 (i)(6), and in accordance with our implementing regulations (42 C.F.R. Part 90). In preparing this document, ATSDR has collected relevant health data, environmental data, and community health concerns from the Environmental Protection Agency (EPA), state and local health and environmental agencies, the community, and potentially responsible parties, where appropriate. This document represents the agency’s best efforts, based on currently available information, to fulfill the statutory criteria set out in CERCLA section 104 (i)(6) within a limited time frame. To the extent possible, it presents an assessment of potential risks to human health. Actions authorized by CERCLA section 104 (i)(11), or otherwise authorized by CERCLA, may be undertaken to prevent or mitigate human exposure or risks to human health. In addition, ATSDR will utilize this document to determine if follow-up health actions are appropriate at this time.

This document has previously been provided to EPA and the affected state in an initial release, as required by CERCLA section 104 (i) (6) (H) for their information and review. Where necessary, it has been revised in response to comments or additional relevant information provided by them to ATSDR. This revised document has now been released for a 45-day public comment period. Subsequent to the public comment period, ATSDR will address all public comments and revise or append the document as appropriate. The public health assessment will then be reissued. This will conclude the public health assessment process for this site, unless additional information is obtained by ATSDR which, in the agency’s opinion, indicates a need to revise or append the conclusions previously issued.

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PUBLIC HEALTH ASSESSMENT

COMMERCE STREET PLUME

WILLISTON, CHITTENDEN COUNTY, VERMONT

EPA FACILITY ID: VTD098352545

Prepared by:

Division of Community Health Investigations  
Eastern Branch  
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Agency for Toxic Substances and Disease Registry

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## Foreword

Congress established the Agency for Toxic Substances and Disease Registry, ATSDR, in 1980 under the Comprehensive Environmental Response, Compensation, and Liability Act, also known as the Superfund law. This law set up a process to identify and clean up our country's worst hazardous waste sites. The U.S. Environmental Protection Agency (EPA) is responsible for implementing the law to ensure the investigation and clean-up of the sites.

Since 1986, Superfund law has required ATSDR to conduct a public health assessment for each of the sites proposed for the EPA National Priorities List (NPL). The aim of these evaluations is to find out if people are being exposed to hazardous substances and, if so, whether that exposure is harmful and be stopped or reduced. If appropriate, ATSDR also conducts public health assessments when petitioned by concerned individuals. Public health assessments are carried out by environmental and health scientists from ATSDR and from the states with which ATSDR have cooperative agreements. The public health assessment process allows ATSDR scientists and public health assessment cooperative agreement partners' flexibility in document format when presenting findings about the public health impact of hazardous waste sites. The flexible format allows health assessors to convey to affected populations important public health messages in a clear and expeditious way.

**Exposure:** As the first step in the evaluation, ATSDR scientists review environmental data to see how much contamination is at a site, where it is, and how people might come into contact with it. Generally, ATSDR does not collect its own environmental sampling data but reviews information provided by EPA, other government agencies, businesses, and the public. When there is not enough environmental information available, the report will indicate what further sampling data is needed.

**Health Effects:** If the review of the environmental data shows that people have or could come into contact with hazardous substances, ATSDR scientists evaluate whether these contacts may result in harmful effects. ATSDR recognizes that children, because of their play activities and their growing bodies, may be more vulnerable to these effects. As a policy, unless data are available to suggest otherwise, ATSDR considers children to be more sensitive and vulnerable to hazardous substances. Thus, the health impact to the children is considered first when evaluating the health threat to a community. The health impacts to other high-risk groups within the community (such as the elderly, chronically ill, and people engaging in high risk practices) also receive special attention during the evaluation.

ATSDR uses existing scientific information, which can include the results of medical, toxicological, and epidemiologic studies to evaluate the possible health effects that may result from exposures. The science of environmental health is still developing, and sometimes scientific information on the health effects of certain substances is not available.

**Community:** ATSDR also needs to learn what people in the area know about the site and what concerns they may have about its impact on their health. Consequently, throughout the evaluation process, ATSDR actively gathers information and comments from the people who live or work near a site, including residents of the area, civic leaders, health professionals, and

community groups. To ensure that the report responds to the community's health concerns, an early version is also distributed to the public for their comments. All the public comments related to the document are addressed in the final version of the report.

**Conclusions:** The report presents conclusions about the public health threat posed by a site. Ways to stop or reduce exposure will then be recommended in the public health action plan. ATSDR is primarily an advisory agency, so usually these reports identify what actions are appropriate to be undertaken by EPA or other responsible parties. However, if there is an urgent health threat, ATSDR can issue a public health advisory warning people of the danger. ATSDR can also recommend health education or pilot studies of health effects, full-scale epidemiology studies, disease registries, surveillance studies or research on specific hazardous substances.

**Comments:** If, after reading this report, you have questions or comments, we encourage you to send them to us.

Letters should be addressed as follows:

Attention: Manager, ATSDR Records Center  
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## Summary

### Introduction

The Commerce Street Plume site was proposed for inclusion on the EPA National Priorities List (NPL) on September 23, 2004, with a final rule in 2005. ATSDR is required to conduct public health assessments of sites proposed for the NPL under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) and its amendments. The US Environmental Protection Agency (EPA) completed its Remedial Investigation (RI) in July 2012

In 1985, elevated levels of volatile organic compounds (VOCs), primarily trichloroethylene (TCE), were identified in groundwater under commercial buildings on Commerce Street and under homes on South Brownell Road and Kirby Avenue. Several private drinking water wells that tapped the contaminated shallow aquifer were identified and subsequently placed on public water.

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## ***Conclusions***

ATSDR reached the following two conclusions from its public health assessment of the site.

Conclusion 1	Currently there is no ongoing exposure to VOCs from contaminated drinking water, groundwater, surface water or indoor air.
Basis for Conclusion	Residents in the area were placed on public water in mid-1985 and their contaminated private wells were capped and closed. Soils were not contaminated and the only prior indoor air problem was due to an improperly vented sump pump pulling shallow groundwater and vented TCE in basement air. That pump was reinstalled correctly in 1986, and there was no further indoor air problem.
Conclusion 2	Four households down gradient from the Commerce Street Plume Site may have been exposed to TCE contaminated drinking water for up to six years, from 1979 until mid-1985, at levels, which may have increased their risk for harmful health effects.
Basis for Conclusion	Levels of TCE in the four private drinking water wells prior to mid-1985 were elevated. Based on the latest science on how TCE affects people's health, ATSDR believes the TCE levels were high enough to have possibly caused harmful health effects. Pregnant women who drank water from any of the four wells may have been at an increased risk for fetal heart malformations among their babies. Adults and children who drank water from any of the four wells may have been at an increased risk for immune system and kidney impacts. The risk of cancer was elevated for the wells with the highest concentration of TCE (590 µg/L). The cancer risks calculated for the remaining three wells were considered to be low to moderately elevated.

### ***Recommendations***

1. ATSDR recommends continued monitoring of TCE concentrations in groundwater.
2. ATSDR recommends that no one in the future use shallow groundwater as a source of potable water.

### ***Next Steps***

ATSDR will review new data if it becomes available.

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## Background Information

The Agency for Toxic Substances and Disease Registry (ATSDR) is a federal agency within the U.S. Department of Health and Human Services and is located in Atlanta, Georgia. ATSDR is required to conduct public health assessments of sites proposed for the EPA National Priorities List (NPL) under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) and its amendments. The Commerce Street Plume site was proposed for inclusion on the NPL on September 23, 2004, with a final rule in 2005. EPA completed its Remedial Investigation (RI) in July 2012.

The purpose of this Public Health Assessment (PHA) is to determine whether residents living near the Commerce Street Plume may have been harmed by, exposures to VOCs (in the past or currently) contained in drinking water from residential wells, indoor air, and surface water and the public health actions needed to reduce future exposures.

## *Site Description and History*

### **Site Description**

The Commerce Street Plume is located at an industrial park in Williston, Chittenden County, Vermont. The property occupies one acre at 96 Commerce Street and currently includes one 6,000 square foot building. Various manufacturing and electroplating operations occurred on the property since 1960. The two primary sources of contamination on the property are an unlined lagoon and a leach field, which were both created to dispose of liquid waste. Plating rinse water and sludge wastes containing heavy metals and solvents were disposed of into the unlined lagoon and the leach field intermittently through 1984.

From 1979 to 1986, Mitec leased the property for manufacturing of electronic and microwave components. After a Mitec employee expressed concern to the Vermont Agency of Environmental Conservation (VT AEC) in March 1982, the State found the company in violation of hazardous waste regulations for the disposal of chromium contaminated wastes.

In 1985, four residential private drinking water wells down gradient of the lagoon and leach field were contaminated with TCE at concentrations up to 590 parts per billion (ppb) and perchloroethylene (PCE) up to 12 ppb. Concentrations of TCE above federal Maximum Contaminant Levels (MCLs) were identified by the Vermont Department of Health (VT DOH). VT DOH sampled most of the private wells in the area and placed the entire area on public water.

Numerous groundwater, surface water, sediment, residential indoor air, and soil sampling events occurred between 1984 and 2002. In 1987 and 1988, concentrations of TCE and PCE were detected in groundwater monitoring wells at concentrations up to 3,300 ppb and 660 ppb, respectively. In 1996, soil samples collected by the Vermont Agency for Natural Resources (VT ANR) indicated TCE concentrations up to 1,790 ppb directly downgradient of the leach field. Additional studies detected dichloroethylene (DCE) up to 180 ppb, chromium at 3.4 ppb, TCE at 170 ppb, and vinyl chloride at 11 ppb in wetlands and the nearby unnamed stream, which flows into Muddy Brook and ultimately the Winooski River. In 1999, groundwater samples taken by

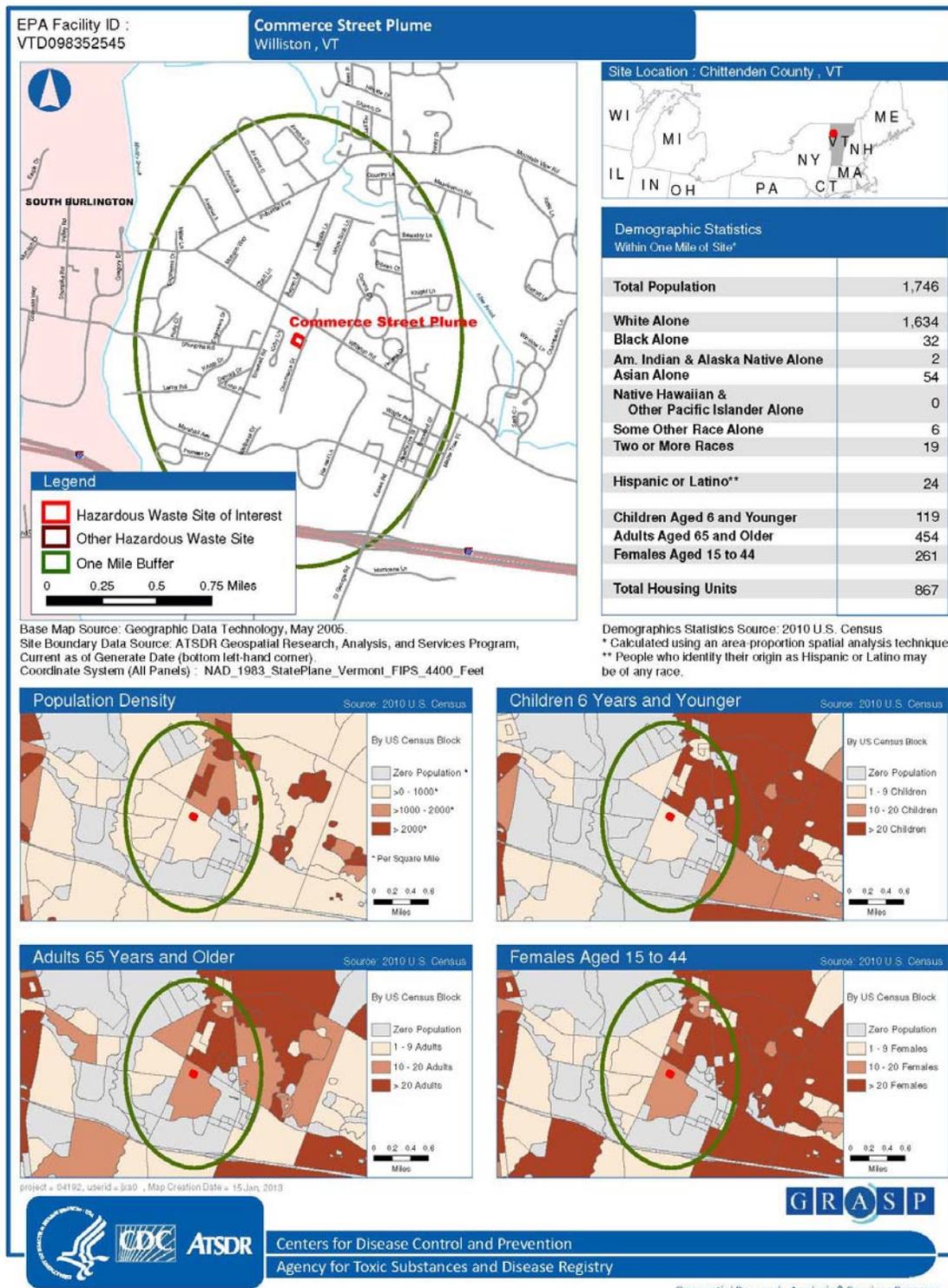
the VT ANR found TCE in groundwater at levels as high as 90,000 ppb downgradient of the former Mitec facility. In 2002, EPA detected elevated levels of 11 VOCs and 13 total metals in monitoring wells located throughout the industrial park and surrounding residential area.

Groundwater contamination continues to be detected directly downgradient of the property and has the potential to migrate to private and public water supplies serving approximately 1,575 people within 4 miles of the property.

### ***Demographic Information***

As shown in Figure 1, the total population within a one-mile radius of the Commerce Street Plume Site was 1,746 as per the 2010 US Census. Minorities made up roughly six percent of the population. Sensitive populations including children under the age of six, women of childbearing age (age 15 to 44 years old), and elderly over 65 years old represented 48 percent of the total population.

**Figure 1. Commerce Street Map and Population Data**



## **Community Health Concerns**

Members of the community have expressed concerns about cancer in general. Cancer is discussed in the section *named Possible Cancer Health Effects* on page 17 of this document.

## **Environmental Contamination Information**

The Commerce Street Plume site information and environmental sampling data evaluated in this document were obtained primarily from historical site file documents from the Vermont Department of Environmental Conservation (VT DEC) and more recent site reports from the U.S. Environmental Protection Agency (EPA). The EPA site reports include Nobis Engineering, Inc. (for EPA Region 1) “2010 Data Summary, Commerce Street Plume Superfund Site, Williston, Vermont, Remedial Investigation/Feasibility Report”, June 2011 [Nobis 2011]; and EPA “HRS Documentation Record, Commerce Street Plume, September 2004) [EPA 2004].

The data that ATSDR evaluated includes environmental sampling data from private residential drinking water wells, from air inside private residences, and from surface water in an unnamed stream. In addition, ATSDR reviewed but did not evaluate environmental sampling data from groundwater monitoring wells and site soils because the data do not reflect actual exposure point concentrations.

### ***Groundwater Contamination***

Four residential private drinking water wells downgradient of the former lagoon and leach field at 96 Commerce Street were found to be contaminated with TCE at concentrations of up to 590 parts per billion (ppb). Concentrations of TCE above federal MCLs were identified by the Vermont Department of Health (VT DOH) in 1985<sup>1</sup>. In addition, indoor air samples collected in residences downgradient from the property showed VOCs at elevated levels around basement sump-pumps, but not in living spaces. The drinking water wells were subsequently closed, and residents were provided with an alternate drinking water supply.

Numerous groundwater, surface water, sediment, residential indoor air, and soil sampling events occurred between 1984 and 2002. In 1987 and 1988, concentrations of TCE and PCE were detected in groundwater up to 3,300 ppb and 660 ppb, respectively. In 1996, soil samples collected by VT ANR indicated TCE concentrations up to 1,790 ppb directly downgradient of the leach field. Additional studies detected DCE up to 180 ppb, chromium at 3.4 ppb, TCE at 170 ppb, and vinyl chloride at 11 ppb in wetlands and the nearby unnamed stream, which flows into Muddy Brook and ultimately the Winooski River. In 1999, groundwater samples taken by the VT ANR found TCE in groundwater at levels as high as 90,000 ppb downgradient of the former facility. In 2002, EPA detected elevated levels of 11 VOCs and 13 metals in monitoring wells located throughout the industrial park and surrounding residential area.

There are presently no active private drinking water wells within a mile of the Commerce Street Plume. Groundwater contamination continues to be detected directly downgradient of the

property and has the potential to migrate to private and public water supplies serving approximately 1,575 people within 4 miles of the property.

Table 1 lists the maximum concentrations of TCE in four private residential drinking water wells that had any detection of TCE sampled in 1985. The table also lists the cancer and non-cancer drinking water comparison values for TCE.

**Table 1. TCE Concentrations in Water Samples from 1985 for Four Residential Wells with TCE Detected**

<i>Well ID*</i>	<i>TCE Conc. (µg/L)</i>	<i>Comparison Value (CV) – Non-cancer†</i>		<i>Comparison Value (CV) – Cancer†</i>		<i>Max Conc &gt; Lowest CV?</i>
		<i>Value (µg/L)</i>	<i>Source</i>	<i>Value (µg/L)</i>	<i>Source</i>	
A	590	5	RMEG-c	0.76	CREG	<b>Yes</b>
B	190	5	RMEG-c	0.76	CREG	<b>Yes</b>
C	120	5	RMEG-c	0.76	CREG	<b>Yes</b>
D	44	5	RMEG-c	0.76	CREG	<b>Yes</b>

\*Wells are listed in order of decreasing TCE concentration with no relation to well location

† RMEG-c: Reference Dose Media Evaluation Guides for Children’s Exposure.

CREG: Cancer Risk Evaluation Guide

## **Exposure Pathway Information**

At the Commerce Street Plume site, ATSDR identified past household use of water from residential wells as a completed exposure pathway.

### ***Completed Exposure Pathways from Past Household Use of Water from Residential Wells***

Contaminants from the Commerce Street Plume site entered groundwater beneath the site, moved with the groundwater, and eventually reached residential wells along South Brownell Road. People who used water from these wells for drinking or other household purposes, such as showering, bathing, or cooking, were exposed to VOCs in the water. Table 2 shows completed exposure pathways.

Exposure to VOCs from household use of residential well water could have occurred in the following ways:

- *Ingestion:* People could have drunk the water or eaten food prepared using the water.
- *Inhalation:* People could have breathed in VOCs that volatilized (moved into the air) from the water during showering, bathing, or other household use
- *Dermal contact:* People could have absorbed VOCs through their skin during showering, bathing, or other household use.

Exposure to VOCs from household use of residential well water occurred when people living on South Brownell Road were using VOC contaminated private wells as their source of drinking water. Exposure began when VOCs in the groundwater first entered the wells and ended when the residents were connected to the City of Williston water system (in 1985). It is believed that the VOCs did not enter the ground water before 1979. In 1984, complaints of odors were received by VT DOH from residents and the wells were tested.

### ***Eliminated Exposure Pathways***

An analysis of exposure pathways identified several that were judged to be unlikely sources of exposure. Therefore, the following pathways were eliminated from further consideration for the reasons provided below. Table 3 presents additional information on the eliminated exposure pathways.

- Household use of contaminated groundwater: Exposure to contaminated groundwater from the Commerce Street Plume ceased in 1985, when the four contaminated private wells were taken off line and all residents in the area were connected to the Town of Williston water system.

- Surface water (in nearby stream): The nearby stream that has been impacted by contaminants is too small for swimming or wading, and access to the stream is difficult due to heavy vegetation along both sides.
- Vapor intrusion (indoor air): The levels of TCE and PCE were measured in all the homes that had their wells tested. Only one of the homes had elevated TCE in indoor air and it was determined to be due to an improperly vented sump pump. The pump was drawing on the contaminated shallow aquifer and venting TCE to the basement air. The pump was reinstalled to vent outside the home and the TCE levels were no longer detectible. No other homes had detectible TCE in indoor air. Soil gas measurements have not found elevated TCE, and the plume has been dissipating over the past 30 years.

**Table 2. Completed Exposure Pathways for the Commerce Street Plume Site**

<i>Pathway Name</i>	<i>Environmental Media and Transport Mechanisms</i>	<i>Point of Exposure</i>	<i>Route of Exposure</i>	<i>Exposed Population</i>	<i>Time of Exposure</i>	<i>Chemicals</i>	<i>Notes</i>
Past Household Use of Residential Well Water	Movement of contaminant from source to groundwater	Residences with private drinking water wells which were contaminated by VOCs	Ingestion, Inhalation, Direct skin contact	Residents who formerly used contaminated private wells for household uses	Past	VOCs (PCE, TCE).	VOCs were discovered in several residential drinking water wells along S. Brownell Rd in mid- 1985. The wells were promptly closed & the affected homes connected to the municipal water system
Past Vapor Intrusion (Indoor Air)	Movement of contaminant from groundwater through soil and into air inside buildings	Indoor air in homes located above areas of contaminated groundwater	Inhalation	Residents	Past	VOCs (PCE, TCE).	VOCs have been detected in the groundwater, and were detected in indoor air of one of the residences with an improperly vented sump pump. The pump was reinstalled to vent outside and VOCs were no longer detectible in indoor air.

**Table 3. Eliminated Exposure Pathways for the Commerce Street Plume Site**

<i>Pathway Name</i>	<i>Environmental Media and Transport Mechanisms</i>	<i>Point of Exposure</i>	<i>Route of Exposure</i>	<i>Exposed Population</i>	<i>Time of Exposure</i>	<i>Chemicals</i>	<i>Notes</i>
Household Use of Residential Well Water	Movement of contaminant from source to groundwater	Residences with private drinking water wells (which may be currently contaminated or become contaminated in the future)	Ingestion, Inhalation, Direct skin contact	Residents using private drinking water wells for household uses	Present & Future	VOCs (e.g., PCE, (TCE).	<b>NO EXPOSURE.</b> The wells have been closed and the residences have been connected to the Town of Williston public water since the mid 1980s.
Surface Water (in Unnamed Stream)	Movement of contaminant from groundwater to surface water	Unnamed stream behind buildings on east side of Commerce St.	Ingestion, Inhalation	Persons swimming in stream	Past, Present, Future	VOCs (e.g., PCE, (TCE).	<b>NO EXPOSURE.</b> The unnamed stream is too small for swimming, & access is restricted by heavy vegetation along both sides
Vapor Intrusion (Indoor Air)	Movement of contaminant from groundwater through soil and into air inside buildings	Indoor air in homes located above areas of contaminated groundwater	Inhalation	Residents	Present & Future	VOCs (PCE, TCE).	<b>NO EXPOSURE.</b> The levels of VOCs were measured in all the homes that had their wells tested. Only one of the homes had elevated TCE in indoor air and it was determined to be due to an improperly vented sump pump. The pump was reinstalled to vent outside the home and the TCE levels were no longer detectible.

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## Health Effects Evaluation

Exposure to VOCs (TCE) from household use of residential well water was a completed exposure in the past when people living on South Brownell Road were using VOC contaminated private wells for their source of drinking water. Exposures began when TCE first entered the wells and ended in 1985 when the homes were connected to the City of Williston water system. Residents complained of chemical smells in the water in early 1984. TCE was assumed not enter the wells until at least 1979 when VOC contaminated wastes were first discharged into an unlined lagoon behind the building at 96 Commerce Street. As such, the maximum amount of time that the residents on South Brownell Rd. were exposed to TCE from their drinking water wells was estimated to be no more than 6 yrs. (1979–1985). The actual exposure period is not known and could have been shorter than 6 yrs. depending on how long it took for contaminants discharged into the lagoon to seep into groundwater beneath the lagoon and how long it took the contaminated groundwater to travel to the wells. ATSDR used the maximum exposure period of 6 years to estimate the “worst case” TCE drinking water exposure doses for these wells.

In general, ingestion (drinking) is the most significant source of exposure to hazardous substances in water from residential drinking water wells. However, for VOCs inhalation through breathing and dermal skin contact, from showering, bathing, and other indoor water use, can make a significant contribution to the total exposure dose, defined as the total amount of contaminant that enters a person’s body. The extent of these non-ingestion exposures is difficult to determine; one common method used to estimate VOC exposure doses resulting through inhalation and dermal contact is to assume that they are approximately equal to the dose from ingestion [ATSDR 2005]. Therefore, for the purposes of this evaluation, ATSDR estimated the total exposure dose of TCE from household use of residential well water by **doubling** the ingestion dose. The ingestion dose was calculated using TCE well water concentrations and standard default values.

### *Potential Health Effects from TCE Exposure*

#### **Possible Non-cancer Effects**

Ingestion and inhalation studies in animals indicate that one of the principle targets of TCE exposure include harmful effects to the immune system resulting from damage to the thymus gland. Additional studies in animals indicated that TCE exposure in pregnant mice resulted in developmental problems (fetal heart malformations) in their offspring [ATSDR 1997, EPA 2012a]. A recently released epidemiologic study concluded that maternal residence in areas where soil vapor intrusion of TCE into indoor air was associated with cardiac defects [Forand et al., 2012]. Although the study did not evaluate a dose-response relationship, it does provide further support that cardiac effects are the appropriate toxicological endpoint in humans and supports the use of the animal studies for the Reference Dose (RfD) and RfC. It also validates the route extrapolation from oral to inhalation in the RfC derivation. ATSDR has adopted the EPA RfD and RfC as its chronic oral Minimal Risk Level (MRL) and chronic inhalation MRL, respectively.

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EPA identified three principle and two supporting animal studies as the basis of the Reference Dose (RfD) for non-cancerous health effects [EPA 2011]. The findings of each study, including the study effect levels, which are used to evaluate TCE exposures at the four Commerce Street wells, are discussed briefly below.

#### Three Principle RfD Studies: Developmental and Immune System Effects

- A study of rats exposed to TCE in drinking water during gestation identified a small risk (1%) of fetal heart malformation among their offspring at the modeled effect level of 0.0051 mg/kg/day. The effect level was derived by converting various animal doses in the study (referred to as a bench mark dose modeling level or BMDL) to a dose equivalent in humans (referred to as the human equivalent dose or HED). The estimated effect level of 0.0051 mg/kg/day for the Johnson study is called the HED<sub>99,BMDL01</sub> [Johnson et al. 2003, EPA 2011]. An uncertainty factor of 10 was applied by EPA in the derivation of the RfD.

The major milestones for fetal cardiac development in humans take place over a period of approximately 3 weeks in the first trimester; therefore, even short-term exposures to TCE must be considered when evaluating the potential increased risk for fetal heart malformations.

- A study of mice exposed to TCE in drinking water for 30 weeks identified immune system effects, specifically decreased thymus weights, at an effect level of 0.048 mg/kg/day [Keil et al. 2009]. The effect level is based on the Lowest Observed Adverse Effect Level (or LOAEL) in the animal study and was converted to an equivalent dose in humans (HED) to derive the HED<sub>99,LOAEL</sub> of 0.048 mg/kg/day. An uncertainty factor of 100 was applied by EPA in the derivation of the RfD [EPA 2011].
- A study of mice exposed during gestation and for up to 8 weeks following birth through drinking water identified a decreased immune response at the effect level, a LOAEL, of 0.37 mg/kg/day [Peden-Adams et al. 2006]. An uncertainty factor of 1,000 was applied by EPA in the derivation of the RfD [EPA 2011].

#### Two Supporting RfD Studies: Kidney effects

- A study of rats exposed to TCE for 104 weeks by gavage reported an increased risk (5%) for kidney toxicity at the effect level, a HED<sub>99,BMDL05</sub>, of 0.0034 mg/kg/day, which represents a human equivalent dose converted from the results of bench mark dose modeling from the animal study [NTP 1988]. An uncertainty factor of 10 was applied by EPA in the derivation of the RfD [EPA 2011].

- A study of rats exposed to TCE in air for 4 weeks identified a risk (10%) of increased kidney weights. The effect level, a HED<sub>99,BMDL10</sub>, is 0.0079 mg/kg/day [Woolhiser et al. 2006]. EPA applied an uncertainty factor of 10 in the derivation of the RfD [EPA 2011].

While the effect levels for these studies are different, the application of the study-specific uncertainty factors results in similar doses ranging from 0.00034-0.00051 mg/kg/day. EPA chose 0.0005 mg/kg/day as the chronic oral RfD.

The estimated TCE doses for individuals possibly affected by this site exceed EPA's chronic oral RfD. Therefore, Table 4 presents the comparison of the exposure doses for the Commerce Street wells (for children and adults) with the health effect levels from the available animal studies that were used to make non-cancer health conclusions. It is important to note that TCE doses that approach or exceed the effects levels from the studies may pose an increased risk for health effects. The non-cancer health conclusions for the four wells evaluated are also presented in Table 4.

**Table 4. Comparison of Estimated Exposure Doses to Non-Cancer Study Effect Levels for TCE-Contaminated Private Wells**

TCE Water Concentration (µg/L)	Estimated Doses (mg/kg/day)		Exposure Doses Compared to Study Effect Levels			
			Fetal Heart Effects (0.0051 mg/kg/day)	Immune/Thymus Effects (0.048 mg/kg/day)	Immune/Developmental Effects (0.37 mg/kg/day)	Kidney Effects (0.0034-0.0079 mg/kg/day)
44	Young children	0.012	NA*	A	A	E
	Adults	0.0031	A	A	A	A
120	Young children	0.034	NA*	A	A	E
	Adults	0.0085	E	A	A	E
190	Young children	0.054	NA*	E	A	E
	Adults	0.014	E	A	A	E
590	Young children	0.17	NA*	E	A	E
	Adults	0.042	E	A	A	E

**Notes:**

*A = Exposure dose approaches the study effect level.*

*E = Exposure dose exceeds the study effect level. NA\* = Not applicable—dose applies to pregnant women.*

- The estimated exposure doses for pregnant women who regularly drank water from these four wells exceeded the chronic oral RfD of 0.0005 mg/kg/day
- The TCE exposure doses for pregnant women who regularly drank water from these four wells approached or exceeded the health effect level for fetal heart malformations. Therefore, they may have had an increased risk of having children with heart defects; however, the exact risk is unknown.
- The TCE exposure doses for adults and children who drank water from these four wells approached or exceeded the health effect levels for immune system effects, including decreased thymus gland weight and delayed immune response, as well as kidney effects. Therefore, they may have had an increased risk of these health effects; however, the exact risk is unknown.

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## Possible Cancer Effects

The National Toxicology Program (NTP) classifies TCE as reasonably anticipated to be a human carcinogen. In humans, occupational exposure to TCE was associated with excess incidences of several cancers, particularly liver cancer, non-Hodgkin's lymphoma, and kidney cancer [NTP 2011]. Animal studies showed that TCE exposure caused tumors in mice and rats at several different organs, including liver and kidney, by inhalation or oral exposure) [NTP 2011]. The International Agency for Research on Cancer (IARC) has determined that TCE is a probable human carcinogen based on epidemiological studies showing increased rates of liver cancer and non-Hodgkin's lymphoma, primarily in workers who may have been exposed to TCE on the job, and animal studies showing increased numbers of liver and kidney tumors upon oral administration [IARC 1995]. EPA characterizes TCE as carcinogenic to humans by all routes of exposure [EPA 2011a; EPA 2011c]. This conclusion was based on human epidemiologic studies showing associations between human exposure to TCE and kidney cancer, non-Hodgkin's lymphoma, and liver cancer.

In September 2011, EPA published a revised IRIS oral cancer slope factor for TCE of 0.046 (mg/kg/day)<sup>-1</sup> reflecting total incidence of kidney, non-Hodgkin's lymphoma, and liver cancers [EPA 2011b; EPA, 2011c]. The following evaluation uses the latest EPA oral cancer slope factor to evaluate the potential for increased risk of cancer resulting from past TCE exposures at this site.

EPA's latest assessment characterizes TCE as carcinogenic to humans by all routes of [EPA 2011b]. An oral slope factor of 0.046 (mg/kg/day)<sup>-1</sup> is based on an increased risk of kidney cancer, non-Hodgkin's lymphoma and liver cancer [EPA 2011c]. EPA concluded that, for kidney cancer, TCE is carcinogenic by a mutagenic mode of action, which means that it acts by modifying the DNA of the cell. As a result, increased early-life susceptibility is assumed for kidney cancer, and age-dependent adjustment factors (ADAFs) are used for the kidney cancer component of the total cancer risk when estimating age-specific cancer risks [EPA 2011b]. ADAFs are factors by which cancer risk is multiplied to account for increased susceptibility to mutagenic compounds early in life – standard ADAFs are 10 (for ages below 2 years old), 3 (for ages 2 up to 16 years old), and 1 (for ages 16 years old and greater) [EPA 2005].

For a given period of exposure, the component oral CSF is multiplied by the daily exposure dose, appropriate ADAF, and a fraction corresponding to the fraction of a 78-year lifetime under consideration, to obtain the increased risk of cancer.

The cancer risks calculated in this health assessment represent an increased cancer risk associated with exposure to TCE that is in addition to an individual's baseline cancer risk. For example, an estimated cancer risk of 1 in 1,000,000 (or  $1 \times 10^{-6}$ ) means that, in addition to their baseline cancer risk, one additional person out of a million people exposed to TCE may develop cancer during their lifetime.

Estimated increased cancer risks from past exposure to TCE were calculated assuming a worst case that TCE exposure began at birth and occurred for up to 6 years (the maximum amount of

time that residents could have been exposed to TCE-contaminated groundwater from their drinking water wells.) This corresponds to the period beginning when TCE first entered the wells (1979 or later) and ending and when the residences with contaminated wells were connected to the municipal water system (1985).

Table 5 summarizes the estimated increased cancer risks from a child 0-6 years old drinking and bathing in TCE-contaminated water daily for 6 years for each of the residential wells where TCE was detected. The estimated cancer risk for three of the four wells is above the upper end of EPA’s general target risk range of 1 in 1,000,000 to 1 in 10,000 (or  $1 \times 10^{-6}$  to  $1 \times 10^{-4}$ ).

The actual increased cancer risks are probably lower than the estimated, worst-case risks shown in Table 5. The method used to calculate EPA’s cancer slope factor assumes that high-dose animal data can be used to estimate the risk for low-dose exposures in humans. The method also assumes that no safe level exists for exposure. Little experimental evidence exists to confirm or refute those two assumptions. In addition, the method used to calculate the cancer slope factor computes the upper 95<sup>th</sup> percent confidence limit for the risk. The actual increased cancer risk can be lower, perhaps by several orders of magnitude [EPA 1989].

**Table 5. Estimated Cancer Risk From TCE Contaminated Private Wells**

<i>TCE Water Concentration (µg/L)</i>	<i>Estimated Increased Cancer Risk Exposure Group (Duration): Birth to 6 yrs. old (6 yrs.)</i>	<i>Cancer Risk per 100,000 Exposed People</i>
44	$2.5 \times 10^{-5}$	2.5
120	$6.8 \times 10^{-5}$	6.8
190	$1.1 \times 10^{-4}$	11
590	$3.3 \times 10^{-4}$	33

**Health Outcome Data:**

The health department’s cancer registry has no records of any public inquiries or any previous cancer statistical analyses near this site. Health outcome data is not relevant given the past exposures ceased in 1985 and the small number of households (four) impacted.

## **Child Health Considerations**

In communities faced with air, water, or food contamination, the many physical differences between children and adults demand special emphasis. Children could be at greater risk than are adults from certain kinds of exposure to hazardous substances. Children play outdoors and sometimes engage in hand-to-mouth behaviors that increase their exposure potential. Children are shorter than are adults; this means they breathe dust, soil, and vapors close to the ground. A child's lower body weight and higher intake rate results in a greater dose of hazardous substance per unit of body weight. If toxic exposure levels are high enough during critical growth stages, the developing body systems of children can sustain permanent damage. Finally, children are dependent on adults for access to housing, for access to medical care, and for risk identification. Thus, adults need as much information as possible to make informed decisions regarding their children's health. ATSDR is committed to evaluating children's sensitivities at areas such as the Commerce Street Plume Site.

ATSDR found that children from birth to six years old would have been the most sensitive receptor to TCE contaminated drinking water. The cancer risk evaluations, kidney toxicity and thymus effects were calculated for the first six years.

## Conclusions

1. Currently there is no on-going exposure to VOCs from contaminated drinking water, groundwater, surface water or indoor air. Residents in the area were placed on public water in mid-1985 and their contaminated private wells were capped and closed. Soils were not contaminated and the only prior indoor air problem was due to an improperly vented sump pump pulling shallow groundwater and vented TCE in basement air. That pump was reinstalled correctly in 1986 and there was no further indoor air problem.
2. Four households downgradient from the Commerce Street Plume Site may have been exposed to TCE contaminated drinking water for up to six years, from 1979 until mid-1985, at levels, which may have increased their risk for harmful health effects. Levels of TCE in the four private drinking water wells prior to mid-1985 were elevated. Based on the latest science on how TCE affects people's health, ATSDR believes the TCE levels were high enough to have possibly caused harmful health effects. Pregnant women who drank water from any of the four wells may have been at an increased risk for fetal heart malformations among their babies. Adults and children who drank water from any of the four wells may have been at an increased risk for immune system and kidney impacts. The risk of cancer was elevated for the wells with the highest concentration of TCE (590 µg/L). The cancer risks calculated for the remaining three wells were considered to be low to moderately elevated.

## Recommendations

1. ATSDR recommends continued monitoring of TCE concentrations in groundwater.
2. ATSDR recommends that no one in the future use shallow groundwater as a source of potable water.

## Public Health Action Plan

ATSDR will share findings of this public health assessment with EPA, Vermont and the public for their comments.

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## Appendix A: ATSDR Glossary of Environmental Health Terms

The Agency for Toxic Substances and Disease Registry (ATSDR) is a federal public health agency with headquarters in Atlanta, Georgia, and 10 regional offices in the United States. ATSDR's mission is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and diseases related to toxic substances. ATSDR is not a regulatory agency, unlike the U.S. Environmental Protection Agency (EPA), which is the federal agency that develops and enforces environmental laws to protect the environment and human health.

This glossary defines words used by ATSDR in communications with the public. It is not a complete dictionary of environmental health terms. If you have questions or comments, call ATSDR's toll-free telephone number, 1-800-CDC-INFO (1-800-232-4636).

### **Acute**

Occurring over a short time [compare with chronic].

### **Acute exposure**

Contact with a substance that occurs once or for only a short time (up to 14 days) [compare with intermediate duration exposure and chronic exposure].

### **Adverse health effect**

A change in body function or cell structure that might lead to disease or health problems

### **Cancer**

Any one of a group of diseases that occur when cells in the body become abnormal and grow or multiply out of control.

### **Cancer risk**

A theoretical risk for getting cancer if exposed to a substance every day for 70 years (a lifetime exposure). The true risk might be lower.

### **Cancer Risk Evaluation Guides (CREGs)**

CREGs are media-specific comparison values that are used to identify concentrations of cancer-causing substances that are unlikely to result in an increase of cancer rates in an exposed population. ATSDR develops CREGs using EPA's cancer slope factor (CSF) or inhalation unit risk (IUR), a target risk level ( $10^{-6}$ ), and default exposure assumptions. The target risk level of  $10^{-6}$  represents a theoretical risk of 1 excess cancer cases in a population of 1 million. The default exposure assumptions account for ingestion rates and body weights. CREGs are only available for adult exposures—no CREGs specific to childhood exposures are available.

### **Carcinogen**

A substance that causes cancer.

### **Case study**

A medical or epidemiologic evaluation of one person or a small group of people to gather information about specific health conditions and past exposures.

**CERCLA** [see Comprehensive Environmental Response, Compensation, and Liability Act of 1980]

**Chronic**

Occurring over a long time [compare with acute].

**Chronic exposure**

Contact with a substance that occurs over a long time (more than 1 year) [compare with acute exposure and intermediate duration exposure]

**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.

**Completed exposure pathway** [see exposure pathway].

**Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)**

CERCLA, also known as Superfund, is the federal law that concerns the removal or cleanup of hazardous substances in the environment and at hazardous waste sites. ATSDR, which was created by CERCLA, is responsible for assessing health issues and supporting public health activities related to hazardous waste sites or other environmental releases of hazardous substances. This law was later amended by the Superfund Amendments and Reauthorization Act (SARA).

**Concentration**

The amount of a substance present in a certain amount of soil, water, air, food, blood, hair, urine, breath, or any other media.

**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.

**Disease prevention**

Measures used to prevent a disease or reduce its severity.

**Disease registry**

A system of ongoing registration of all cases of a particular disease or health condition in a defined population.

**DOD**

United States Department of Defense.

**DOE**

United States Department of Energy.

**Dose (for chemicals that are not radioactive)**

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**

United States Environmental Protection Agency.

## **Exposure**

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

## **Exposure assessment**

The process of finding out how people come into contact with a hazardous substance, how often and for how long they are in contact with the substance, and how much of the substance they are in contact with.

## **Exposure, No Harm Expected**

ATSDR concludes that exposure to a substance or pathway is not expected to harm people’s health.

## **Exposure pathway**

The route a substance takes from its source (where it began) to its end point (where it ends), and how people can come into contact with (or get exposed to) it. An exposure pathway has five parts: a source of contamination (such as an abandoned business); an environmental media and transport mechanism (such as movement through groundwater); a point of exposure (such as a private well); a route of exposure (eating, drinking, breathing, or touching), and a receptor population (people potentially or actually exposed). When all five parts are present, the exposure pathway is termed a completed exposure pathway.

## **Exposure registry**

A system of ongoing follow-up of people who have had documented environmental exposures.

## **Feasibility study**

A study by EPA to determine the best way to clean up environmental contamination. A number of factors are considered, including health risk, costs, and what methods will work well.

## **Geographic information system (GIS)**

A mapping system that uses computers to collect, store, manipulate, analyze, and display data. For example, GIS can show the concentration of a contaminant within a community in relation to points of reference such as streets and homes.

## **Groundwater**

Water beneath the earth’s surface in the spaces between soil particles and between rock surfaces [compare with surface water].

## **Hazard**

A source of potential harm from past, current, or future exposures.

## **Hazardous waste**

Potentially harmful substances that have been released or discarded into the environment.

**Health consultation**

A review of available information or collection of new data to respond to a specific health question or request for information about a potential environmental hazard. Health consultations are focused on a specific exposure issue. Health consultations are therefore more limited than a public health assessment, which reviews the exposure potential of each pathway and chemical [compare with public health assessment].

**Ingestion**

The act of swallowing something through eating, drinking, or mouthing objects. A hazardous substance can enter the body this way [see route of exposure].

**Inhalation**

The act of breathing. A hazardous substance can enter the body this way [see route of exposure].

**Intermediate duration exposure**

Contact with a substance that occurs for more than 14 days and less than a year [compare with acute exposure and chronic exposure].

**Lack of Data or Information**

ATSDR cannot currently conclude whether a substance or pathway could harm people's health.

**Long-term Exposure, Chronic Hazard**

ATSDR concludes that a substance or pathway from an exposure for more than a year in duration could harm people's health. "This is a public health hazard."

**Lowest-observed-adverse-effect level (LOAEL)**

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

**mg/kg**

Milligram per kilogram.

**mg/cm<sup>2</sup>**

Milligram per square centimeter (of a surface).

**mg/m<sup>3</sup>**

Milligram per cubic meter; a measure of the concentration of a chemical in a known volume (a cubic meter) of air, soil, or water.

**Migration**

Moving from one location to another.

**Minimal risk level (MRL)**

An ATSDR estimate of daily human exposure to a hazardous substance at or below which that substance is unlikely to pose a measurable risk of harmful (adverse), noncancerous effects. MRLs are calculated for a route of exposure (inhalation or oral) over a specified time period (acute, intermediate, or chronic). MRLs should not be used as predictors of harmful (adverse) health effects [see reference dose].

**Morbidity**

State of being ill or diseased. Morbidity is the occurrence of a disease or condition that alters health and quality of life.

**Mortality**

Death. Usually the cause (a specific disease, a condition, or an injury) is stated.

**National Priorities List for Uncontrolled Hazardous Waste Sites (National Priorities List or NPL)**

EPA's list of the most serious uncontrolled or abandoned hazardous waste sites in the United States. The NPL is updated on a regular basis.

**National Toxicology Program (NTP)**

Part of the Department of Health and Human Services. NTP develops and carries out tests to predict whether a chemical will cause harm to humans.

**No Exposure, No Harm Expected**

ATSDR concludes that the substance or pathway will not harm people's health, because people have not been in contact or otherwise exposed to the substance or pathway.

**No-observed-adverse-effect level (NOAEL)**

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

**NPL** [see National Priorities List for Uncontrolled Hazardous Waste Sites]

**Physiologically based pharmacokinetic model (PBPK model)**

A computer model that describes what happens to a chemical in the body. This model describes how the chemical gets into the body, where it goes in the body, how it is changed by the body, and how it leaves the body.

**Point of exposure**

The place where someone can come into contact with a substance present in the environment [see exposure pathway].

**Population**

A group or number of people living within a specified area or sharing similar characteristics (such as occupation or age).

**Potentially responsible party (PRP)**

A company, government, or person legally responsible for cleaning up the pollution at a hazardous waste site under Superfund. There may be more than one PRP for a particular site.

**ppb**

Parts per billion.

**ppm**

Parts per million.

**Prevalence**

The number of existing disease cases in a defined population during a specific time period [contrast with incidence].

**Prevention**

Actions that reduce exposure or other risks, keep people from getting sick, or keep disease from getting worse.

**Public availability session**

An informal, drop-by meeting at which community members can meet one-on-one with ATSDR staff members to discuss health and site-related concerns.

**Public comment period**

An opportunity for the public to comment on agency findings or proposed activities contained in draft reports or documents. The public comment period is a limited time period during which comments will be accepted.

**Public health action**

A list of steps to protect public health.

**Public health advisory**

A statement made by ATSDR to EPA or a state regulatory agency that a release of hazardous substances poses an immediate threat to human health. The advisory includes recommended measures to reduce exposure and reduce the threat to human health.

**Public health assessment (PHA)**

An ATSDR document that examines hazardous substances, health outcomes, and community concerns at a hazardous waste site to determine whether people could be harmed from coming into contact with those substances. The PHA also lists actions that need to be taken to protect public health [compare with health consultation].

**Public health hazard categories**

Public health hazard categories are statements about whether people could be harmed by conditions present at the site in the past, present, or future. One or more hazard categories might be appropriate for each site. The five public health hazard categories are:

- Category 1. Short-term exposure, acute hazard
- Category 2. Long-term exposure, chronic hazard
- Category 3. Lack of data
- Category 4. Exposure, no harm expected
- Category 5. No exposure, no harm expected

**Public health statement**

The first chapter of an ATSDR toxicological profile. The public health statement is a summary written in words that are easy to understand. The public health statement explains how people might be exposed to a specific substance and describes the known health effects of that substance.

**Public health surveillance**

The ongoing, systematic collection, analysis, and interpretation of health data. This activity also involves timely dissemination of the data and use for public health programs.

**Public meeting**

A public forum with community members for communication about a site.

**RCRA** [see Resource Conservation and Recovery Act (1976, 1984)]

**Receptor population**

People who could come into contact with hazardous substances [see exposure pathway].

**Reference Concentration (RfC):** An estimate of a continuous inhalation exposure for a given duration to a group of people that is not expected to cause adverse health effects over a lifetime.

**Reference dose (RfD)**

An EPA estimate, with uncertainty or safety factors built in, of the daily lifetime dose of a substance that is unlikely to cause harm in humans.

**Reference Dose Media Evaluation Guides (RMEG)**

If no MRL is available to derive an EMEG, ATSDR develops RMEGs using EPA's reference doses (RfDs) and default exposure assumptions, which account for variations in intake rates between adults and children. EPA's reference concentrations (RfCs) serve as RMEGs for air exposures. Like EMEGs, RMEGs represent concentrations of substances (in water, soil, and air) to which humans may be exposed without experiencing adverse health effects. RfDs and RfCs consider lifetime exposures, therefore, RMEGs apply to chronic exposures.

**Registry**

A systematic collection of information on persons exposed to a specific substance or having specific diseases [see exposure registry and disease registry].

**Remedial investigation**

The CERCLA process of determining the type and extent of hazardous material contamination at a site.

**Resource Conservation and Recovery Act (1976, 1984) (RCRA)**

This Act regulates management and disposal of hazardous wastes currently generated, treated, stored, disposed of, or distributed.

**RFA**

RCRA Facility Assessment. An assessment required by RCRA to identify potential and actual releases of hazardous chemicals.

**RfD** [see reference dose]

**Risk**

The probability that something will cause injury or harm.

**Risk reduction**

Actions that can decrease the likelihood that individuals, groups, or communities will experience disease or other health conditions.

**Risk communication**

The exchange of information to increase understanding of health risks.

**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** [see uncertainty factor]

**SARA** [see Superfund Amendments and Reauthorization Act]

**Sample**

A portion or piece of a whole. A selected subset of a population or subset of whatever is being studied. For example, in a study of people the sample is a number of people chosen from a larger population [see population]. An environmental sample (for example, a small amount of soil or water) might be collected to measure contamination in the environment at a specific location.

**Sample size**

The number of units chosen from a population or an environment.

**Short-term Exposure, Acute Hazard**

ATSDR concludes that a substance or pathway is an urgent public health hazard from short term exposures of less than a year in duration.

**Soil gas or Soil Vapor**

Air existing in void spaces in the soil between the groundwater and the ground surface. These gases may include vapor of hazardous chemicals as well as air and water vapor.

**Solvent**

A liquid capable of dissolving or dispersing another substance (for example, acetone or mineral spirits).

**Source of contamination**

The place where a hazardous substance comes from, such as a landfill, waste pond, incinerator, storage tank, or drum. A source of contamination is the first part of an exposure pathway.

**Special populations**

People who might be more sensitive or susceptible to exposure to hazardous substances because of factors such as age, occupation, sex, or behaviors (for example, cigarette smoking). Children, pregnant women, and older people are often considered special populations.

**Stakeholder**

A person, group, or community who has an interest in activities at a hazardous waste site.

**Statistics**

A branch of mathematics that deals with collecting, reviewing, summarizing, and interpreting data or information. Statistics are used to determine whether differences between study groups are meaningful.

**Substance**

A chemical.

**Substance-specific applied research**

A program of research designed to fill important data needs for specific hazardous substances identified in ATSDR's toxicological profiles. Filling these data needs would allow more accurate assessment of human risks from specific substances contaminating the environment. This research might include human studies or laboratory experiments to determine health effects resulting from exposure to a given hazardous substance.

**Superfund** [see Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) and Superfund Amendments and Reauthorization Act (SARA)]

**Superfund Amendments and Reauthorization Act (SARA)**

In 1986, SARA amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) and expanded the health-related responsibilities of ATSDR. CERCLA and SARA direct ATSDR to look into the health effects from substance exposures at hazardous waste sites and to perform activities including health education, health studies, surveillance, health consultations, and toxicological profiles.

**Surface water**

Water on the surface of the earth, such as in lakes, rivers, streams, ponds, and springs [compare with groundwater].

**Surveillance** [see public health surveillance]

**Survey**

A systematic collection of information or data. A survey can be conducted to collect information from a group of people or from the environment. Surveys of a group of people can be conducted by telephone, by mail, or in person. Some surveys are done by interviewing a group of people [see prevalence survey].

**Synergistic effect**

A biologic response to multiple substances where one substance worsens the effect of another substance. The combined effect of the substances acting together is greater than the sum of the effects of the substances acting by themselves [see additive effect and antagonistic effect].

**Teratogen**

A substance that causes defects in development between conception and birth. A teratogen is a substance that causes a structural or functional birth defect.

**Toxic agent**

Chemical or physical (for example, radiation, heat, cold, microwaves) agents that, under certain circumstances of exposure, can cause harmful effects to living organisms.

**Toxicological profile**

An ATSDR document that examines, summarizes, and interprets information about a hazardous substance to determine harmful levels of exposure and associated health effects. A toxicological profile also identifies significant gaps in knowledge on the substance and describes areas where further research is needed.

**Toxicology**

The study of the harmful effects of substances on humans or animals.

**Tumor**

An abnormal mass of tissue that results from excessive cell division that is uncontrolled and progressive. Tumors perform no useful body function. Tumors can be either benign (not cancer) or malignant (cancer).

**Uncertainty factor**

Mathematical adjustments for reasons of safety when knowledge is incomplete. For example, factors used in the calculation of doses that are not harmful (adverse) to people. These factors are applied to the lowest-observed-adverse-effect-level (LOAEL) or the no-observed-adverse-effect-level (NOAEL) to derive a minimal risk level (MRL). Uncertainty factors are used to account for variations in people's sensitivity, for differences between animals and humans, and for differences between a LOAEL and a NOAEL. Scientists use uncertainty factors when they have some, but not all, the information from animal or human studies to decide whether an exposure will cause harm to people [also sometimes called a safety factor].

**Vapor Intrusion:**

(VI) is a process by which chemicals in soil or groundwater migrate to indoor air above a contaminated site.

**Volatile organic compounds (VOCs)**

Organic compounds that evaporate readily into the air. VOCs include substances such as benzene, toluene, methylene chloride, and methyl chloroform.

**Other glossaries and dictionaries:**

Environmental Protection Agency (<http://www.epa.gov/OCEPAterms/>)

National Library of Medicine (NIH)

(<http://www.nlm.nih.gov/medlineplus/mplusdictionary.html>)

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## **Appendix B: Explanation of ATSDR's Public Health Evaluation Process**

### **Screening Process**

(ATSDR, 2002) In evaluating environmental sampling data, ATSDR uses comparison values (CVs) to determine which chemicals to examine more closely.

CVs are health-based contaminant concentrations found in a specific media (air, soil, or water) and are used to screen contaminants for further evaluation. CVs incorporate assumptions of daily exposure to the chemical and a standard amount of air, water, and soil that someone might inhale or ingest each day.

(ATSDR, 2002)

As health-based thresholds, CVs are set at a concentration below which no known or anticipated adverse human health effects are expected to occur. Different CVs are developed for cancer and non-cancer health effects. Non-cancer levels are based on valid toxicological studies for a chemical, with appropriate safety factors included, and the assumption that small children and adults are exposed every day. Cancer levels are based on a one-in-a-million excess cancer risk for exposure to contaminated soil or drinking contaminated water every day for 70 years. For chemicals for which both cancer and non-cancer CVs exist, we use the lower level to be protective. Exceeding a CV does not mean that health effects will occur, just that more evaluation is needed. (ATSDR, 2002)

Comparison Values (CVs) are chemical and media-specific concentrations in air, soil, and drinking water that are used by ATSDR health assessors and others to identify environmental contaminants at hazardous waste sites that require further evaluation. CVs incorporate assumptions of daily exposure to the chemical and, in the case of soil and water, a standard amount that someone may likely take into their body each day. CVs are conservative and non-site specific. CVs are based on health guidelines with uncertainty or safety factors applied to ensure that they are adequately protective of public health. (ATSDR, 2002)

The comparison of environmental data with ATSDR CVs is one of the first steps in the public health assessment process. The results of this screening step give health assessors an understanding of the priority contaminants at a site. When a contaminant is detected at a concentration less than its respective CVs, exposure is not expected to result in health effects and it is not considered further as part of the public health assessment process. It should be noted that contaminants detected at concentrations that exceed their respective CVs, do not necessarily represent a health threat. Instead, the results of the CV screening identify those contaminants that warrant a more detailed, site-specific evaluation to determine whether health effects may occur. CVs are not intended to be used as environmental clean-up levels.

(ATSDR, 2002)

CVs can be based on either carcinogenic or non-carcinogenic effects. Cancer-based CVs are calculated from the U.S. Environmental Protection Agency's (EPA) oral cancer slope factor (CSF) or inhalation unit risk (IUR). CVs based on cancerous effects account for a lifetime exposure (70 years) with a calculated excess lifetime cancer risk of 1 extra case per 1 million exposed people. Non-cancer values are calculated from ATSDR's Minimal Risk Levels (MRLs), EPA's Reference Doses (RfDs), or EPA's Reference Concentrations (RfCs). When a cancer and non-cancer CV exists for the same chemical, the lower of these values is used in the data comparison for public health protectiveness. (ATSDR, 2002)

ATSDR's comparison values are defined below. (ATSDR, 2002)

### Minimal Risk Levels

Minimal Risk Levels (MRLs) are an estimate of the daily human exposure to a substance that is likely to be without appreciable risk of adverse health effects during a specified duration of exposure. MRLs are based only on non-carcinogenic effects. MRLs are derived for acute (1-14 days), intermediate (15-364 days), and chronic (365 days and longer) durations for the oral and inhalation routes of exposure. Currently, MRLs for dermal exposure are not derived.

$$MRL = \frac{NOAEL \text{ (or LOAEL)}}{UF}$$

- MRL = Minimal Risk Level (mg/kg/day)
- NOAEL = No Observed Adverse Effect Level (mg/kg/day)
- LOAEL = Lowest Observed Adverse Effect Level (mg/kg/day)
- UF = Uncertainty Factor (unit less)

### Environmental Media Evaluation Guides (Derived from ATSDR MRLs)

Environmental Media Evaluation Guides (EMEGs) represent concentrations of substances in water, soil, and air to which humans may be exposed during a specified period of time (acute, intermediate or chronic) without experiencing non-cancerous adverse health effects. EMEGs have been calculated using MRLs and default exposure assumptions. The default exposure assumptions account for variations in water and soil ingestion between adults and children. Standard default exposure parameters currently used by ATSDR are included below.

Child	Body Weight = 10 kg
	Water Ingestion Rate = 1 liter/day
	Soil Ingestion Rate = 200 mg/day
	Pica Soil Ingestion Rate = 5,000 mg/day

Adult                      Body Weight = 70 kg  
                                  Water Ingestion Rate = 2 liters/day  
                                  Soil Ingestion Rate = 100 mg/day

### **Drinking Water EMEGs**

$$EMEG_w = \frac{MRL \times BW}{IR}$$

EMEG<sub>w</sub>                      = Environmental Media Evaluation Guides for Water (mg/L)  
MRL                         = ATSDR's Minimal Risk Level (mg/kg/day)  
BW                          = Body Weight (kg)  
IR                            = Drinking Water Ingestion Rate (L/day)

### **Soil EMEGs**

$$EMEG_s = \frac{MRL \times BW}{IR \times CF}$$

EMEG<sub>s</sub>                      = Environmental Media Evaluation Guides for Soil (mg/kg)  
MRL                         = ATSDR's Minimal Risk Level (mg/kg/day)  
BW                          = Body Weight (kg)  
IR                            = Soil Ingestion Rate (mg/day)  
CF                            = Conversion Factor of 10<sup>-6</sup> (kg/mg)

### **Air EMEGs**

EMEGs for the evaluation of inhalation exposures to airborne contaminants are ATSDR's inhalation MRLs. The inhalation MRLs are expressed in concentration units of micrograms/cubic meter (µg/m<sup>3</sup>) or parts per billion (ppb) and no additional mathematical calculation is required. The same air EMEG value is used for all segments of the population.

## Reference Dose Media Evaluation Guides (Derived from EPA RfDs and RfCs)

ATSDR develops Reference Dose Media Evaluation Guides (RMEGs) for soil and drinking water using EPA's RfDs and default exposure assumptions. EPA's RfCs serve as RMEGs for air exposures. Like EMEGs, RMEGs represent concentrations of substances (in water, soil, and air) to which humans may be exposed without experiencing non-cancerous, adverse health effects. RfDs and RfCs consider lifetime exposures; therefore, RMEGs apply to chronic exposures.

### Drinking Water RMEGs

$$RMEG_w = \frac{RfD \times BW}{IR}$$

RMEG<sub>w</sub> (mg/L) = Reference Dose Media Evaluation Guides for Drinking Water

RfD = EPA's Reference Dose (mg/kg/day)  
 BW = Body Weight (kg)  
 IR = Drinking Water Ingestion Rate (L/day)

### Soil RMEGs

$$RMEG_s = \frac{RfD \times BW}{IR \times CF}$$

RMEG<sub>s</sub> = Reference Dose Media Evaluation Guides for Soil (mg/kg)  
 RfD = EPA's Reference Dose (mg/kg/day)  
 BW = Body Weight (kg)  
 IR = Soil Ingestion Rate (mg/day)  
 CF = Conversion Factor of 10<sup>-6</sup> (kg/mg)

## Cancer Risk Evaluation Guides

Cancer Risk Evaluation Guides (CREGs) are media-specific comparison values that are used to identify concentrations of cancer-causing substances that are unlikely to result in a significant increase of cancer rates in an exposed population. ATSDR develops CREGs using EPA's CSF or IUR, a target risk level (10<sup>-6</sup>), and default exposure assumptions. The target risk level of 10<sup>-6</sup> represents a calculated risk of 1 excess cancer cases in an exposed population of 1 million. At this time, CREGs are available only for adult exposures.

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### **Drinking Water CREGs**

$$CREG_w = \frac{TR \times BW \times CF}{IR \times CSF}$$

CREG <sub>w</sub>	= Cancer Risk Evaluation Guide for Drinking Water (µg/L or ppb)
TR	= Target Risk Level (10 <sup>-6</sup> )
BW	= Body Weight (70 kg)
CF	= Conversion Factor (1000 µg/mg)
IR	= Drinking Water Ingestion Rate (2 L/day)
CSF	= EPA's Oral Cancer Slope Factor [(mg/kg/day) <sup>-1</sup> ]

### **Soil CREGs**

$$CREG_s = \frac{TR \times BW \times CF}{IR \times CSF}$$

CREG <sub>s</sub>	= Cancer Risk Evaluation Guide for Soil (mg/kg)
TR	= Target Risk Level (10 <sup>-6</sup> )
BW	= Body Weight (70 kg)
CF	= Conversion Factor (10 <sup>6</sup> mg/kg)
IR	= Soil Ingestion Rate (100 mg/day)
CSF	= EPA's Oral Cancer Slope Factor [(mg/kg/day) <sup>-1</sup> ]

### **Air CREGs**

$$CREG_A = \frac{TR}{IUR}$$

CREG <sub>A</sub>	= Cancer Risk Evaluation Guide for Air (µg/m <sup>3</sup> )
TR	= Target Risk Level (10 <sup>-6</sup> )
IUR	= EPA's Inhalation Unit Risk [(µg/m <sup>3</sup> ) <sup>-1</sup> ]

When none of the ATSDR comparison values listed above are available, environmental guidelines from other sources, such as those described below, may be considered:

### **Regional Screening Levels**

Regional Screening Levels (RSLs) are chemical-specific concentrations developed by EPA for individual contaminants in air, drinking water and soil that may warrant further investigation or site cleanup. RSLs are not cleanup standards.

### **Maximum Contaminant Levels**

Maximum Contaminant Levels (MCLs) are enforceable standards set by EPA for the highest level of a contaminant allowed in drinking water. MCLs are set as close to MCL goals (the level of a contaminant in drinking water below which there is no known or expected risk to health) as feasible using the best available treatment technology and taking cost into consideration.

### **Estimating Exposure Dose**

Contaminants present at levels above the CVs are further evaluated to determine whether exposures to the contaminants may be a health hazard given site-specific exposure situations. For exposures occurring by inhalation, the air concentration of the contaminant can be compared directly with health guideline air concentrations. For other pathways, we estimate the *exposure dose*, or the amount of contaminant that gets into a person's body. The exposure dose is typically expressed as milligrams of contaminant per kilogram of body weight of the person exposed, per day (mg/kg/day). This allows comparison with toxicological studies, which express dose in the same units. Exposure that occurs through skin absorption may be converted to either an exposure dose or equivalent air concentration, depending on the other exposure routes being considered.

In estimating the exposure doses, ATSDR made assumptions about weight and other body characteristics of children and adults exposed, how they may be exposed, and how often they may be exposed to allow estimation of site- and pathway-specific exposure dose. The following sections detail the exposure assumptions and calculation of exposure dose for the pathways evaluated in this PHA.

### ***Exposure to Contaminants in Private Well Water***

The overall exposure doses were estimated for pregnant women and young children – considered the most sensitive to environmental toxins in many situations. For estimating cumulative cancer risk, exposure was estimated for various age groups. Assumed body weights and drinking water ingestion rates are presented in Table B-1 [EPA 2011a].

**Table B-1. Estimates for Body Weight & Drinking Water Ingestion**

<b>Group</b>	<b>Body Weight in Kilograms (Pounds)*</b>	<b>Ingestion of Drinking Water in Liters per Day<sup>†</sup></b>
Children from Birth Up to 1 Year Old	7.8 kg (17 lb.)	1.1 L/day
Pregnant Women	63.2 kg (139 lb.)	2.6 L/day
Children from Birth Old Up to Age 2	9.6 kg (21 lb.)	1.0 L/day
Children from 2 Years Old Up To Age 16	36.6 kg (80 lb.)	1.5 L/day
Children from 16 Years Old Up To Age 21	71.6 kg (158 lb.)	2.5 L/day
Adults Greater Than 21 Years Old	80 kg (176 lb.)	3.0 L/day
<p>Sources:</p> <p>* Weight for pregnant women obtained from Table 8-10 of [EPA 2011a], median weight of women ages 15 to 44. Weight for children and adults obtained from Table 8-1 of [EPA 2011a], recommended values for body weight (males and females combined). (Weighted averages used to obtain body weight for specific age ranges listed in this table.)</p> <p><sup>†</sup> Obtained from Tables 3-1 and 3-3 of [EPA 2011a], consumers-only ingestion of drinking water, 95<sup>th</sup> percentile. (Weighted averages used to obtain ingestion for specific age ranges listed in this table.)</p> <p>kg = kilogram    lb. = pound    L/day = liters per day</p>		

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As discussed in the main body of the document, the estimated ingestion exposure was doubled to account for additional exposure from inhalation and dermal exposure. The overall exposure dose is given by the following equation:

$$\text{Dose in mg/kg/day} = 2 \times \frac{\text{Concentration in } \frac{\mu\text{g}}{\text{L}} \times \text{Ingestion in } \frac{\text{L}}{\text{day}}}{1000 \frac{\mu\text{g}}{\text{mg}} \times \text{Body weight in kg}}$$

For example, the calculation of exposure of a child weighing 7.8 kg drinking 1.1 liter per day of water containing 100  $\mu\text{g/L}$  TCE is estimated as:

$$2 \times \frac{100 \frac{\mu\text{g}}{\text{L}} \times 1.1 \frac{\text{L}}{\text{day}}}{1000 \frac{\mu\text{g}}{\text{mg}} \times 7.8 \text{ kg}} = 0.03 \text{ mg/kg/day}$$

### ***Evaluating Non-cancer Health Effects***

The calculated exposure doses are compared to an appropriate health guideline for that chemical. Health guideline values are considered safe doses; that is, health effects are unlikely below this level. The health guideline value is based on valid toxicological studies for a chemical, with appropriate safety factors built in to account for human variation, animal-to-human differences, and/or the use of the lowest study doses that resulted in harmful health effects (rather than the highest dose that did not result in harmful health effects). For non-cancer health effects, the following health guideline values are used.

#### ***Minimal Risk Level (MRLs) – Developed by ATSDR***

An MRL is an estimate of daily human exposure – by a specified route and length of time – to a dose of chemical that is likely to be without a measurable risk of adverse, non-cancerous effects. An MRL should not be used as a predictor of adverse health effects. A list of MRLs can be found at <http://www.atsdr.cdc.gov/mrls/index.html>.

### ***Reference Concentration (RfC) – Developed by EPA***

The RfC is an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfC considers both toxic effects of the respiratory system (portal-of-entry) and effects peripheral to the respiratory system (extrarespiratory effects). RfCs can be found at <http://www.epa.gov/iris>.

### ***Reference Dose (RfD) – Developed by EPA***

The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. RfDs can be found at <http://www.epa.gov/iris>.

### ***Maximum Contaminant Level (MCL) – Developed by EPA***

The MCL is the highest level of a contaminant that is allowed by the EPA in public drinking water systems. MCLs are enforceable standards set as close as feasibly possible to levels below which there is no known or expected risk to health, using the best available treatment technology and taking cost into consideration.

If the estimated exposure dose for a chemical is less than the health guideline value, then the exposure is unlikely to cause a non-cancer health effect in that specific situation. If the exposure dose for a chemical is greater than the health guideline, then the exposure dose is compared to known toxicological values for that chemical and is discussed in more detail in the public health assessment. These toxicological values are doses derived from human and animal studies that are summarized in the ATSDR Toxicological Profiles and in current scientific literature. A direct comparison of site-specific exposure and doses to study-derived exposures and doses that cause adverse health effects is the basis for deciding whether health effects are likely or not.

### **Evaluating Cancer Health Effects**

The estimated risk of developing cancer resulting from exposure to the contaminants was calculated by multiplying the site-specific estimated exposure dose by an appropriate cancer slope factor or inhalation unit risk (EPA values can be found at <http://www.epa.gov/iris>). The result estimates the increase in risk of developing cancer after a lifetime of continuous exposure to the contaminant.

If a substance causes cancer by a mutagenic mode of action, there is a greater risk for exposures that occur in early life. A current list of substances EPA considers mutagenic can be found at <http://www.epa.gov/oswer/riskassessment/sghandbook/chemicals.htm>. For these substances, age-dependent adjustment factors (ADAFs) are applied to the risks estimated as follows: An ADAF of 10 is applied for exposures taking place from birth up to 2 years old, and an ADAF of 3 is applied for exposures taking place from age 2 up to age 16. No adjustment is applied for exposures at age 16 or above

The actual increased risk of cancer may be lower than the calculated number, which gives an estimated risk of excess cancer. The methods used to calculate cancer slope factors assume that high-dose animal data can be used to estimate the risk for low dose exposures in humans. The methods also assume that no safe level exists for exposure. Little experimental evidence exists to confirm or refute those two assumptions. Lastly, most methods compute the upper 95th percent confidence limit for the risk. The actual cancer risk can be lower, perhaps by several orders of magnitude

Because of uncertainties involved in estimating cancer risk, ATSDR employs a weight-of-evidence approach in evaluating all relevant data . Therefore, the increased risk of cancer is described in words (qualitatively) rather than giving a numerical risk estimate only. Numerical risk estimates must be considered in the context of the variables and assumptions involved in their derivation and in the broader context of biomedical opinion, host factors, and actual exposure conditions. The actual parameters of environmental exposures must be given careful consideration in evaluating the assumptions and variables relating to both toxicity and exposure.

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The age dependent cancer risk is the sum of the risk for each age interval "i", the cancer risk for exposure by a specified pathway is computed as:

$$\text{Cancer Risk} = \sum_i \frac{C \times IR_i \times EF_i \times ED_i \times ADAF_i \times SF}{BW_i \times AT}$$

where:

- C = Concentration of the chemical in the contaminated environmental medium (soil or water) to which the person is exposed. The units are mg/kg for soil and mg/L for water.
- IR<sub>i</sub> = Intake rate of the contaminated environmental medium for age bin "i". The units are mg/day for soil and L/day for water.
- BW<sub>i</sub> = Body weight of the exposed person for age bin "i" (kg).
- EF<sub>i</sub> = Exposure frequency for age bin "i" (days/year). This describes how often a person is likely to be exposed to the contaminated medium over the course of a typical year.
- ED<sub>i</sub> = Exposure duration for age bin "i" (years). This describes how long a person is likely to be exposed to the contaminated medium during their lifetime.
- AT = Averaging time (days). This term specifies the length of time over which the average dose is calculated. For quantifying cancer risk, "lifetime" exposure employs an averaging time of 70 years (i.e., 70 years × 365 days/year).
- SF = Cancer slope factor (mg/kg-day)<sup>-1</sup>
- ADAF<sub>i</sub> = Age-dependent adjustment factor for age bin "i" (unitless)
-