Health Consultation

MILLSBORO TCE

MILLSBORO, DELAWARE

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Toxic Substances and Disease Registry
Division of Community Health Investigations
Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

A health consultation is a verbal or written response from ATSDR or ATSDR's Cooperative Agreement Partners to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. In order to prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR or ATSDR's Cooperative Agreement Partner which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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HEALTH CONSULTATION

MILLSBORO TCE

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Prepared By:

U.S. Department of Health and Human Services
Agency for Toxic Substances and Disease Registry (ATSDR)
Division of Community Health Investigations

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Acronyms

ATSDR	Agency for Toxic Substances and Disease Registry
CalEPA	California Environmental Protection Agency
CREG	Cancer Risk Evaluation Guides
DNREC	Department of Natural Resources and Environmental Control
DPH	Division of Public Health
EPA	Environmental Protection Agency
gpm	gallons per minute
GAC	Granulated Activated Carbon
HC	Health Consultation
HEC_{99}	Human Equivalent Concentration
HED_{99}	Human Equivalent Dose
ITRC	Interstate Technology and Regulatory Council
MCL	Maximum Contaminant Level
MRL	Minimal Risk Level
NHANES	National Health and Nutrition Examination Survey
NPL	National Priorities List
NOAEL	No Observed Adverse Effect Level
ODW	Office of Drinking Water
ppb	parts per billion
ppm	parts per million
PRP	Potentially Responsible Party
PBPK	Physiologically Based Pharmacokinetic
RfD	Reference Dose
SI	Site Investigation
SIRS	Site Investigation and Restoration Section
TCE	Trichloroethylene
VI	Vapor Intrusion

Millsboro TCE Summary

Introduction

In September 2009, the Millsboro TCE site was proposed to the Environmental Protection Agency's (EPA) National Priorities List (NPL). Under EPA's Engineering Evaluation and Cost Analysis for a Non-time-critical Removal program, the site will remain proposed provided that the Potentially Responsible Party (PRP) complies with EPA's direction.

The Town of Millsboro water distribution system discovered trichloroethylene (TCE) contamination in October 2005. The Delaware Department of Health and Social Services (DHSS) Division of Public Health (DPH) Office of Drinking Water (ODW) issued an immediate do-not-use notice to all residents receiving water from the Town of Millsboro water supply system. The notice was lifted following the installation of a granulated activated carbon (GAC) filtration system that removes the TCE prior to the water entering the distribution system.

A former poultry vaccine manufacturing plant was the source of the TCE. It was used as a heat transfer medium within a closed refrigeration system. A release from this system led to TCE contamination in the soil and eventually in the shallow groundwater aquifer. Two of the three of Millsboro's water supply system wells were contaminated with TCE.

The Agency for Toxic Substances and Disease Registry's (ATSDR) main concern for the site is the exposure of community members to TCE and whether or not that exposure may potentially harm someone's health. The water supply wells became contaminated between annual water tests on October 18, 2004 and October 17, 2005. Therefore, the greatest TCE exposure would result if that contamination began on October 19, 2004 and occurred for the entire year. ATSDR used well water test results from October 17, 2005, through October 17, 2006, to estimate past exposures and possible public health implications.

A carbon filtration system was installed to remove TCE, and the public water supply is meeting drinking water standards for TCE. As long as the treatment system is monitored and maintained, exposure to TCE will not occur.

ATSDR also considered community TCE exposure from vapor intrusion (VI). This is a pathway of concern because residents are located in close proximity to and directly over the TCE groundwater plume. The Department of Natural Resources and Environmental Control (DNREC) conducted two investigations that focused on soil gas and indoor air sampling. Results showed no signs of TCE VI, but more investigation is necessary to adequately characterize the potential for TCE exposure from VI at the site.

Conclusions

ATSDR reached the following three conclusions for community members using Millsboro public water sometime between October 2004 and October 2005.

Conclusion 1 Using Millsboro's public water supply now or in the future will not harm people's health; provided the water continues to meet federal standards.

Conclusion basis Following the installation of the granulated activated carbon (GAC) filters, the water supplied by the Millsboro Water Treatment Facility contains levels of TCE below EPA's maximum contaminant level (MCL) of 5 parts per billion (ppb) and ATSDR's environmental media exposure guideline (EMEG) of 5 ppb. ATSDR's EMEG is an estimated contaminant concentration in a media where noncarcinogenic health effects are unlikely. The low levels in the water supplied by the Millsboro Water Treatment Facility are confirmed through an extensive weekly sampling schedule that has been conducted since the filters were installed. Of note, the reporting limit used in the analysis is 0.5 ppb which is below ATSDR's most protective health-based guideline.

Next steps ATSDR recommends that monitoring and maintenance efforts continue to ensure that water supplied to residents meets federal drinking water standards for TCE.

Conclusion 2 ATSDR determined that past exposure to TCE in the public water supply may have increased Millsboro residents' likelihood of experiencing noncarcinogenic health effects. The increased risk for carcinogenic health effects is low.

Conclusion basis ATSDR calculated the individual and combined cancer risks from ingestion, inhalation, and dermal absorption to TCE contaminated water and increased risks ranged from 3 excess cases in a population of 1,000,000 to 5 excess cancer cases in a population of 100,000. Regarding noncancer health effects, the TCE levels result in doses that could be associated with an increased likelihood of adverse noncancer health conditions. Since a suitable comparison value does not yet exist for the intermediate duration (one year or less) of exposure that was experienced in Millsboro and because the estimated exposure doses exceed EPA's reference dose and reference concentration, ATSDR compared the estimated exposure doses with effect levels from available studies. These effect levels were the human equivalent doses (HED) which were derived by EPA from animal studies (Note: For more information on HEDs, refer to EPA's Toxicological Review of Trichloroethylene (EPA 2011b)). It is important to note that ATSDR took a conservative approach in its estimations and the actual concentration of TCE that people were exposed to is unknown and was likely less than the concentration used in the dose calculations.

Conclusion 3 Data are inadequate to conclude whether there is exposure to TCE by the vapor intrusion (VI) pathway. The information needed to make a decision is not available. ATSDR is working with Department of Natural Resources and Environmental Control – Site Investigation and Restoration Section (DNREC-SIRS) and EPA to gather the needed information.

Conclusion basis Two investigations have been conducted by DNREC that included sampling soil gas and indoor air. Neither investigation found TCE at levels of concern. However, the sampling locations were not located along the central axis of the plume where the highest concentrations of TCE would be expected. Therefore, insufficient evidence exists to state that there is no VI problem. EPA and DNREC-SIRS are working with the PRP to gather data that are needed to characterize the VI pathway.

Next steps ATSDR will work closely with DNREC-SIRS and EPA to obtain necessary VI data. If samples are collected by the PRP and verified by DNREC-SIRS and EPA, ATSDR will analyze the data to determine if VI exists at levels that could prove harmful to someone's health.

Background

Site Description and History

The Millsboro TCE site includes an area of trichloroethylene (TCE) soil and groundwater contamination located at 225 West Dupont Highway, Millsboro, Sussex County, Delaware (EPA 2009a). A variety of poultry vaccine companies were on the site between 1952 and 1999. The TCE was used as a heat transfer medium within a closed refrigeration system. Throughout the late 1980's and late 1990's the removal of a single aboveground storage tank and two underground storage tanks (USTs) occurred on the property. The building was demolished in late 2000 and is currently a vacant grass lot. Prior to the removal and demolition process, the site was included in a facility wide Phase I and Phase II environmental assessment that was conducted in 1998 (Metcalf & Eddy 1998). TCE was not detected in the three soil and two groundwater samples that were collected on the site. In 2001, a "No Further Action" letter was issued by the DNREC Tank Management Branch for groundwater contamination resulting from a leaking UST.

During the week of October 17, 2005, the Delaware Division of Public Health – Office of Drinking Water (DPH-ODW) identified TCE contamination in a new connection in the Dagsboro area to the town of Millsboro's water supply system. The concentration of TCE was 80 ppb which exceeds the 5 ppb maximum contaminant level (MCL). The MCL is set by the Environmental Protection Agency (EPA) and it is the maximum level of a contaminant that is allowed in drinking water (EPA 2009a). The DPH-ODW issued an immediate do-not-use notice to all users of the Town of Millsboro's water supply system (DNREC 2007a). Those affected were supplied bottled water by the municipality until the notice was lifted in December 2005. The contamination was traced back to two of the town's public water supply wells (PW-1 and PW-2). The notice was lifted following the installation of a granulated activated carbon (GAC) filtration system (see Figure 3) that removes TCE prior to the water entering the distribution system. Between October 2005 and September 2009, Millsboro's Water Treatment Facility conducted weekly testing to ensure residents were receiving water that did not contain TCE above the MCL. TCE levels in the drinking water currently supplied by the Millsboro Water Treatment Facility are below levels of detection or if TCE is detected, it is still below EPA's contract required quantitation limit of 0.5 µg/L (EPA 2011a). At the request of Department of Natural Resources and Environmental Control – Site Investigation and Restoration Section (DNREC-SIRS), sampling was taken over by EPA in early September 2009, and since late July 2010, the sampling has been relegated to the PRPs.

In December 2005 DNREC-SIRS along with its contractor, EA Engineering, Science and Technology, began an investigation to find the source of the contamination. The source was eventually traced back to what is now the Millsboro TCE site. Two USTs contained sludge contaminated with TCE. A total of 209 tons of contaminated soil, tanks, and piping were removed by DNREC-SIRS as part of an interim remediation measure (DNREC 2007a). DNREC determined that surface and subsurface soils were contaminated with TCE. DNREC also determined that the source area should be remediated or it could pose an unacceptable human health risk to people who may reside at the site in the future or to construction workers who may perform redevelopment activities at the source area property. In addition, DNREC-SIRS concluded that groundwater flowing beneath the source area towards the town of Millsboro supply wells is contaminated with TCE and poses an unacceptable human health risk to people drinking the untreated water (DNREC 2007a). According to DNREC, there are no private wells close enough to the TCE plume to be impacted.

The site investigation conducted by DNREC-SIRS found TCE levels in source-area monitoring wells as high as 17,000 ppb. Groundwater samples collected from the Millsboro public supply wells PW-1 and PW-2 contained TCE concentrations above the MCL of 5 ppb and ATSDR's environmental media evaluation guide (EMEG) for drinking water of 5 ppb for children and 18 ppb for adults. ATSDR's EMEG is an estimated contaminant concentration in a media where noncarcinogenic health effects are unlikely (ATSDR 2005). PW-1 and PW-2 are approximately 1,500 feet northeast of the source area. PW-3 is adjacent to the contaminated wells, but it is drilled to a greater depth and screened in the confined

Manokin aquifer. It is regularly sampled and TCE has not been detected. See Figure 2 for the spatial relationship between the three public supply wells that were in use in 2006.

TCE contaminated ground water has only been detected in the unconfined aquifer (Columbia aquifer). This is the aquifer from which PW-1 and PW-2 draw their water. Again, ground water withdrawn from PW-1 and PW-2 is treated with GAC. The Millsboro Water Department serves an approximate population of 3,800 in both Millsboro and Dagsboro (ODW 2005).

Since TCE contaminated water was found, the town has since constructed one drinking water well, PW-5, into the deeper Manokin aquifer approximately 1300 feet west of the water treatment facility. This well has been online since July 2010. The water treatment facility's intention was to cease pumping from the contaminated Columbia aquifer and draw their drinking water from the Manokin aquifer which was not contaminated with TCE. However, there was concern for the potential risks associated with the development of the Manokin aquifer as an alternative water supply. Stakeholders hypothesized that pumping from the Manokin aquifer could result in downward migration of TCE contamination from the Columbia aquifer, and it was recommended that a hydrogeologic investigation was needed to determine the strength of the aquitard between the Columbia and Manokin and to evaluate the interconnection between the two aquifers (EPA 2010a). The PRP's contractor carried out a hydrogeologic investigation and provided their findings in an executive summary dated October 29, 2010. They concluded that the continued pumping of the wells in the Columbia aquifer is required to prevent downward migration of TCE contamination. Furthermore, increased pumping in the Manokin aquifer progressively negates the beneficial upward gradient that naturally occurs and that is enhanced by pumping in the Columbia aquifer (Arcadis 2010). Due to the risk of vertical migration of the TCE, the pumping of all of the Town of Millsboro water supply wells should be carefully managed and operational guidance should be developed to provide pumping rates that will maintain plume control.

Because of the volatile nature of TCE, vapor intrusion (VI) should always be a consideration when characterizing a site with groundwater contamination because vapors from contaminated groundwater could migrate into homes and other buildings. In August 2006, indoor air samples were taken from a property adjacent and southeast of the source area. These samples were collected to determine if VI had occurred from the TCE plume. Indoor air samples were taken from the basement, bedroom, family room, and living room. TCE or any of its degradation products were not detected above the reporting limit in any of the indoor air samples (DNREC 2007a). Of note, the reporting limits used in the analysis were all below ATSDR's health based comparison values except for vinyl chloride. The reporting limit used in the analysis for vinyl chloride was 0.2 parts per billion (ppb) and ATSDR's cancer risk evaluation guide (CREG) is 0.04 ppb. This does not mean that the CREG was exceeded, but the sensitivity requested in the analysis cannot definitively show that the CREG was not exceeded. ATSDR's CREGs are estimated contaminant concentrations that are conservative and would be expected to cause no more than one additional excess cancer in one million persons exposed over a lifetime. CREGs are calculated from EPA cancer slope factors.

On September 12, and October 25, 2006, a soil vapor investigation was conducted on a property to the northwest and downgradient of the source. The objective of the investigation was to determine if TCE soil vapor contamination would be a health threat to future residents of the proposed townhomes to be built by Millsboro Properties, LLC. The soil vapor investigation found contamination but concluded that levels did not present an excessive cancer risk (DNREC 2006a). At the time of ATSDR's site visit on June 15, 2010, construction had not begun on the investigated property, and the property remained an undeveloped wooded lot.

Demographics

Available demographic information from the 2010 U.S. Census states that Millsboro has a population of 3,877. The Millsboro Water Treatment Facility supplies water to approximately 3,800 people (ODW 2005). ATSDR calculated demographic information within a one mile radius of the site (see Figure 1).

Community Health Concerns

ATSDR travelled to Millsboro, Delaware in early May 2010 to conduct a site visit and community interviews to identify community concerns related to the Millsboro TCE site. Of the four concerns below, the last three are concerns identified during these community interviews but are unrelated to the subject of this health consultation (HC):

Community Concern: Is the water safe (to drink, shower or use for any purpose)?

Response: Currently, the water that is provided by the Millsboro Water Treatment Facility is suitable to use for any purpose. The water provided to residents is not a threat to health because of the GAC filtration system that Millsboro installed to remove TCE, and the continued effectiveness of this system is confirmed through an extensive weekly sampling schedule that has been conducted since the filters were installed.

Community Concern: During the time period when the water supply was potentially contaminated, how did it affect agriculture or the quality of the produce that was grown in Millsboro?

Response: Studies show that TCE has a low-to-moderate bioconcentration potential in some plants (Schroll, et al., 1994). Therefore, if residents used the Town of Millsboro's water supply to irrigate their gardens or crops during the October 18, 2004 through October 17, 2005 timeframe when TCE contamination occurred, little accumulation in the plant tissue is expected. In addition, TCE is a very volatile compound. Most of it would evaporate into the air during watering and not be absorbed by plants (ATSDR 1997).

Community Concern: Is it safe for children to play and for adults to garden in the soil?

Response: Site related contaminants should not have an impact on the quality of the surface soil of the residences in Millsboro. TCE is mainly a concern in the groundwater and TCE contaminated surface soil has not been found beyond the Site boundaries where approximately 209 tons of contaminated soil and debris was removed on site as part of an interim action (EPA 2009a).

Community Concern: Are local lakes and rivers safe for swimming and fishing?

Response: There is no indication that the water quality of local lakes and rivers has been impacted by any site-related contaminants. The TCE plume is well defined and it has not affected any surface waters, including creeks, streams, rivers, or lakes.

Discussion

TCE background

If one is exposed to TCE, many factors will determine whether they may be harmed. These factors include the amount of TCE that enters the body, the duration and frequency that someone contacts the contaminant, and how one comes in contact with it. One must also consider the other chemicals they are exposed to and their age, sex, diet, family traits, lifestyle, and state of health.

TCE is a nonflammable, colorless liquid at room temperature with a somewhat sweet odor and a sweet, burning taste. TCE is used as a solvent to remove grease from metal parts and is used in a variety of industrial processes. It is also used to make other chemicals. TCE can also be found in some household products, including typewriter correction fluid, paint removers, adhesives, and spot removers. Most

people can begin to smell TCE in air when the concentration approaches 100 parts of TCE per million parts of air (ppm) (ATSDR 1997).

Evaporation of TCE occurs easily because it is a volatile chemical. However, it is rather persistent in the soil and in groundwater. Once the vapors are in the air, about half will be broken down within a week. Once TCE is in surface water, much will evaporate into the air and will take days to weeks to break down in surface water. In groundwater, the breakdown is much slower. Very little TCE breaks down in the soil and it can pass through the soil into groundwater (ATSDR 1997).

Health Effects

Based on the available human and animal studies, it is concluded that TCE poses a potential human health hazard for non-cancer toxicity to the central nervous system, the kidney, the liver, the immune system, the male reproductive system, and the developing fetus. The National Toxicology Program has determined that TCE is reasonably anticipated to be a human carcinogen based on limited evidence of carcinogenicity from studies in humans, sufficient evidence of carcinogenicity from studies in experimental animals, and information from studies on mechanisms of carcinogenesis (NTP 2011).

Exposure Pathways

A critical step in ATSDR's evaluation process is to assess exposure pathways. The goal of exposure pathway evaluations is to identify likely site-specific exposure situations and answer the questions (ATSDR 2005b):

> Is anyone at a given site exposed to environmental contamination?
>
> Under what conditions does this exposure occur?

ATSDR considered the available site specific information and evaluated the ingestion, inhalation, and dermal routes of exposure related to the contaminated groundwater in the Town of Millsboro. The findings are summarized in Table 1.

ATSDR evaluated exposure pathways to determine if people might come into contact with TCE contamination originating from the Millsboro TCE site. Past, current and future exposure conditions were considered and ATSDR determined that past completed pathways and current potential pathways apply to the Millsboro site. Prior to the installation of the GAC filtration system, there was exposure to TCE through the drinking water because the groundwater that Millsboro uses as its public water supply was contaminated. Since the Millsboro site contained contaminated groundwater that was being supplied to households, the residents were exposed via ingestion (by drinking the water), inhalation (from volatilization during a shower or other household uses such as dishwashing and laundry), and dermal contact (when taking a shower or bath). Another potential pathway that deserves investigation is vapor intrusion (VI).

Vapor Intrusion

Vapor intrusion warrants consideration because of the volatile nature of TCE and because the plume runs underneath homes. VI is the migration of volatile organic chemicals (VOCs) from the subsurface-contaminated groundwater and soil through the pore spaces of soil into above buildings. The concentrations of contaminants entering the indoor air from subsurface are dependent upon site and building-specific factors such as building construction, number and spacing of cracks and holes in the foundation, and the impact of the heating and air conditioning system on increasing or decreasing flow from the subsurface. Low confidence is generally attributed to decisions based on one sampling event, unless there is clear evidence that this will result in a health protective decision. Indoor air monitoring that reflects seasonal variations for the site should provide a better basis for an exposure estimate. The California Environmental Protection Agency (CalEPA) guidance recommends at least a late summer/early fall sample in addition to a late winter/early spring sample.

The VI pathway is a potential concern because residents may be exposed to TCE in the indoor air. Currently, indoor air data only exists from the sampling of a property adjacent to the site (DNREC 2006b). None of the samples collected during that August 2006 event detected TCE or its degradation products at levels of concern. The only soil gas samples taken at the site were collected in association with the Millsboro Properties, LLC on 12 September and 25 October 2006. The objective of the investigation was to determine if TCE soil vapor contamination would be an issue for the proposed townhomes at Millsboro Properties, LLC. The townhomes would be constructed on a wooded lot located north of the TCE source site. DNREC calculated the carcinogenic risk for TCE to be 3.8×10^{-8} when evaluating the soil vapor at Millsboro Properties, LLC (DNREC 2006a). Going forward, DNREC and EPA will work closely with the PRP to ensure that sufficient data, either indoor air or soil gas, will be collected to ensure adequate characterization of the VI pathway of the site.

CalEPA also establishes two basic criteria for determining if it is necessary to evaluate VI. First, volatile contaminants must be present in the subsurface, and second, the existing or future buildings at a site must be close to subsurface contamination so that vapor migration into indoor air is possible (CalEPA 2005). EPA recommends that any building within 100 feet laterally or vertically of the contamination plume should be considered a candidate for VI (EPA 2002). The 100 foot distance assumes that no preferential pathways are present and other factors such as fluctuations in groundwater levels are minimal (ATSDR 2005). The contaminant plume in Millsboro has residences located directly over the plume and within 100 lateral feet of the plume. For future VI investigations, ATSDR recommends that the CalEPA (2005), ITRC (2007), EPA (2002), ATSDR (2005a), and DNREC (2007b) guidance be followed.

Table 1: Exposure Pathways Table

Past Completed Pathway

Media	*Source*	*Exposure Point*	*Exposure Route*	*Notes*
Groundwater	Millsboro Public Supply Wells	Drinking water	Ingestion Dermal	Exposure occurred for an unknown duration between Oct. 18, 2004 to Oct. 17, 2005
Indoor Air	Millsboro Public Supply Wells	Showering and other household uses such as dishwashing and laundry	Inhalation Dermal	Residents were exposed to TCE as it volatilized during showering and other household uses such as dishwashing and laundry for an unknown duration between Oct. 18, 2004 to Oct. 17, 2005

Potential Pathway

Media	*Source*	*Exposure Point*	*Exposure Route*	*Notes*
Groundwater	Millsboro Public Supply Wells	Drinking water	Ingestion Dermal Inhalation	Failure of current GAC filtration system could lead to a completed pathway. However, weekly testing ensures system effectiveness
Indoor Air	Vapor Intrusion	Basements / Affected rooms in residence	Inhalation	Indoor air sampling at one property showed no detectable levels but more soil gas / indoor air sampling will be conducted

Public Comment / Update of TCE Evaluation

ATSDR released a draft of this HC for public comment on October 25, 2011. The HC was available for public review and comment at the Millsboro Public Library located at 217 West State Street. The document was also available for viewing or downloading from the ATSDR web site, and the release was announced to local media outlets. The public comment period was open from October 25, 2011 through December 27, 2011.

Only DNREC provided minor comments on the HC, and no comments were received from the general public. However, after releasing the document for public comment, EPA finalized its TCE toxicological review and published revised noncancer and cancer health guideline values on its Integrated Risk Information System (IRIS) (EPA 2011b, EPA 2011c). EPA also finalized its Exposure Factors Handbook in September 2011 (EPA 2011d). ATSDR repeated its evaluation of potential exposures at the site using the 2011 TCE toxicological review and incorporating updated body weight and drinking water ingestion assumptions from the 2011 Exposure Factors Handbook. The reevaluation suggests a wider range of potential health effects from past TCE exposures than were considered in the public comment draft. The section "Potential Health Effects from TCE Exposure" provides further detail.

Because the detailed findings of this HC have changed from the October 2011 draft, ATSDR rereleased this document for public comment to give stakeholders an opportunity to review and provide input on these findings. These comments and ATSDR's responses to these comments are provided in Appendix C.

At the publication of ATSDR's initial draft HC for this site, EPA was reviewing the TCE health hazard oral and inhalation assessments for noncancer effects and the carcinogenicity assessment on IRIS. A draft toxicological review had been published but was not final and could not be cited. In late 2011, EPA finalized the TCE toxicological review and published updated summary information for TCE on IRIS (EPA, 2011b; EPA, 2011c).

ATSDR has revised the evaluation of potential health effects from past TCE exposure to the Millsboro water supply to account for the new information from EPA. This revised evaluation also incorporates new recommendations for exposure assumptions such as body weight and drinking water ingestion rates from EPA's Exposure Factors Handbook, also finalized in September 2011 (EPA, 2011d). As detailed below, compared to the draft evaluation, the new evaluation indicates a wider range of potential noncancer health effects.

Data Limitations

Every attempt was made to accurately assess the potential impact that TCE contamination had on the Millsboro community's health but there were limitations in the environmental data used to make that assessment. When limitations existed, ATSDR chose to be more conservative in its calculations in an effort to be more protective of community's health. Therefore, actual exposures may not have caused the effects that are described in the "Noncancer Health Effects" section of this document.

A major limitation is the lack of drinking water samples taken at the point of exposure. The TCE concentration that is used in the dose calculations is meant to be a health protective estimate of what people were exposed to and was calculated using samples taken from the groundwater supply wells at the water treatment plant. Only one sample of 80 pbb was taken at a point where someone would have been exposed. By using samples taken from the groundwater public supply wells, the concentration may have been less once it reached someone's tap due to volatization of TCE at the treatment facility and as the water traveled from the well to the point of exposure.

Additionally, the exact duration of exposure to contaminated groundwater at this site is unknown. Yearly testing of municipal water quality occurred on October 17, 2004, and October 17, 2005. The 2004 test results did not detect TCE. Conservatively, the water supply could have been contaminated for one year. Of note, Millsboro Water Department was still in compliance with their state-mandated sampling schedule and no TCE was detected above the drinking water standards in the data that ATSDR analyzed prior to the October 2005 sampling event.

Another major uncertainty is the concentration of TCE that was distributed in the public water supply during that time. ATSDR took a health protective approach when selecting the TCE concentration to be used in the dose and cancer risk calculations by using the arithmetic average of the October 17, 2005 to October 17, 2006 sampling data and assuming one year of exposure. This arithmetic average for the year with the highest TCE concentrations overall was used to estimate the exposures (see Appendix A). In addition, an individual could have lowered the concentration of TCE that they were exposed to from their drinking water if they filtered their water using some of the common carbon filters that are widely found on the market today, provided they follow the manufacturer's instructions regarding filter replacement and use.

Of note, there was no site specific data regarding water consumption, shower water flow rates, population's frequency of showering, breathing rate, and body weight. ATSDR used generally accepted default values for these parameters (ATSDR 2005b, CDC 2004, Maslia et al 1996).

Finally, there are no suitable comparison values for TCE that represent the timeframe in which the Millsboro residents were exposed. Residents could have been exposed for one year spanning from October 17, 2004 to October 17, 2005. EPA's reference dose and reference concentration are both intend for comparison to chronic or longer duration exposure scenarios. ATSDR used the human equivalent dose (HED_{99}) for ingestion and the human equivalent concentration (HEC_{99}) for inhalation during showering. The HED and HEC is the dose or concentration derived from animal studies that takes into account the physiologic and pharmacokinetic differences in animal models and man. The EPA used Physiologically Based Pharmacokinetic (PBPK) modeling in the development of their HED and HEC.

Exposure Dose Calculations

For this HC, ATSDR derived exposure doses for eight different age groups. A more detailed description of how ATSDR conducts its screening and exposure dose calculations is included in Appendix B. Exposure doses help determine the extent to which the ingestion of drinking water or inhalation and dermal absorption during showering might be associated with harmful health effects. The following dose calculations are for past exposure using conservative, health protective assumptions. This exposure scenario covered the period of time when TCE contamination of the water supply was possible but the extent of contamination is unknown because no sampling data exist during the timeframe of October 18, 2004 to October 17, 2005. The Millsboro Water Department is required by the state to annually sample for VOCs, and October 18, 2004 was the most recent annual sampling event prior to the detection of TCE in the water supply on October 17, 2005. The October 18, 2004 sampling results showed that TCE was not detected in Millsboro Water Department's samples while the October 17, 2005 water samples did detect TCE in the water supply. Therefore, ATSDR incorporated this estimated timeframe into its exposure scenario and dose calculations because exposure happened after October 18, 2004 and before the discovery of the TCE contamination on October 17, 2005. Of note, ATSDR reviewed sampling data from 1996 to 2010 and TCE was not detected above drinking water standards prior to October 17, 2005. ATSDR then compared the site-specific exposures doses to the observed effect levels reported in critical published studies.

The concentration that was used in the calculations was obtained by taking the arithmetic average of the October 17, 2005, to October 17, 2006, from groundwater public supply well sampling data and assuming one year of exposure. The arithmetic average was chosen because the samples were taken at consistent time intervals and the weight of the data from each sampling event are equal (ATSDR 2005b). Estimates of body weight, water intake, shower times, body surface area, and breathing rates needed to calculate an exposure dose or concentration were obtained from EPA's 2011 Exposure Factors Handbook and are summarized in Tables 2 and 3 below (EPA, 2011e).

***Table 2** Estimates for Body Weight and Drinking Water Ingestion Rate*

Group	Body Weight in Kilograms*	Mean Ingestion of Drinking Water in Milliliters per Day†	95th Percentile Ingestion of Drinking Water in Milliliters per Day†
Birth to <1 year	7.8	504	1,113
1 to <2 years	11.4	308	893
2 to <6 years	17.4	402	1,052
6 to <11 years	31.8	480	1,251
11 to <21 years	64.2	753	2,042
21 to <65 years	80	1,183	2,848
65+ years	76	1,242	2,604
Pregnant Women (15 to 44 years old)	63.2	872	2,589

* Weight for pregnant women obtained from Table 8-10 of (EPA, 2011d), median weight of women ages 15 to 44. Weight for children and adults obtained from Table 8-1 of (EPA, 2011d), recommended values for body weight (males and females combined).

† Obtained from Tables 3-1 and 3-3 of (EPA, 2011d), (Weighted averages were used to obtain ingestion for specific age ranges listed in this table.)

***Table 3** Estimates for Breathing Rates and Shower Times*

Group	Mean Breathing Rate per Minute* in (m^3/min)	Mean Breathing Rate per Day† in (m^3/day)	Mean Time Spent Showering¥ in minutes	Mean time Spent Showering and in Bathroom¥ in minutes	Mean Surface Area of the BodyΩ in cm^2
2 to <6 years	0.011	9.6	11.5	16.5	7,225
6 to <11 years	0.011	12.0	15	20	10,800
11 to <21 years	0.013	15.8	15	20	17,150
21 to <65 years	0.012	15.5	15	20	19,780
65+ years	0.012	13.1	10	15	18,800
Pregnant Women (15 to 44 years old)	0.016	23.4	15	20	19,375

* Values were obtained from Table 6-2 of (EPA 2011d)

† Values were obtained from Table 6-1 of (EPA 2011d)

¥ Values were obtained from Table 16-32 of (EPA 2011d)

Ω Values were obtained from Table 7-1 and 7-9 of (EPA 2011d)

Estimating an exposure dose requires identifying how much, how often, and how long a person may come in contact with a concentration of the contaminant in a specific medium (air, water, soil). The equation and assumptions used to estimate exposure doses from ingesting drinking water and from inhalation and dermal absorption of TCE vapors while showering follow.

Exhibit 1: Exposure Dose Equation for Ingestion

$$D = \frac{C \times IR \times EF}{BW}$$

where,

D	=	exposure dose in milligrams per kilogram per day (mg/kg/day)
C	=	chemical concentration in milligrams per kilogram or liter (mg/kg) or (mg/L)
IR	=	intake rate in milligrams or milliliters per day (mg/day) or (mL/day)
EF	=	exposure factor (unitless)
BW	=	body weight in kilograms (kg)

In the absence of complete exposure-specific information, ATSDR applied several conservative health protective exposure assumptions to estimate exposure doses for TCE. These conservative dose calculations assumptions used an exposure factor of one, the 95th percentile for water intake rates, and assumed TCE was 100% bioavailable. ATSDR evaluated exposure of eight different age groups that drank water from the public water supply. Specifically, ATSDR estimated exposure doses using the following assumptions and intake rates for exposure through ingestion:

- The arithmetic average of the TCE concentrations from October 17, 2005, to October 17, 2006, (0.201 mg/L) was used when calculating the exposure doses. This concentration was calculated using DNREC data (Appendix A) and takes into account the contribution of each well. For instance, Public Well – 1 contributes 260 gallons per minute (gpm) or 35.9% of the total flow. Public Well – 2 contributes 285 gpm or 39.3%, and Public Well – 3 contributes 180 gpm or 24.8% of the total flow in the distribution system (see Appendix A). Through discussions with the water department, the wells are consistently pumped at the aforementioned rates. The October 17, 2005, to October 17, 2006, data were chosen because they were the closest data chronologically to the predicted timeframe of exposure and it contained the highest levels of TCE recorded.
- The water intake rates correspond with the values in Table 2. Of note, these were the 95th percentile water intake rates (EPA 2011d). ATSDR conservatively used the 95th percentile rates for the dose calculations. If the mean intake rates are used, the exposure doses decrease by a factor of approximately three.
- An exposure factor of 1 is a health protective measure to represent an individual being exposed daily. The exposure factor is an expression of how often and how long a person may be contacting a substance in the environment. The exposure factor is calculated by multiplying the frequency of exposure by the exposure duration and dividing by the averaging time (ATSDR 2005).
- The body weights correspond with the values in Table 2. Of note, all weights used in ATSDR's calculations in this HC were taken from EPA's 2011 Exposure Factors Handbook (EPA 2009d).
- The bioavailability of all contaminants was assumed to be 100%—that is, all of the contaminant in media that a person ingested was assumed to enter the bloodstream.

Exhibit 2: Equation for Estimating the Concentration of TCE in Air during Showering

$$C_a = \frac{C_w \times k \times F \times t}{V}$$

where,

C_a = concentration in air (mg/m^3)

C_w = concentration in water (mg/L)

k = volatile mass transfer coefficient (unitless)

F = flow rate in shower (L/min)

t = time in shower (min)

V = bathroom volume (m^3)

ATSDR used the equation in Exhibit 2 to estimate the concentration of TCE in the air during showering. The equation is commonly referred to as the Andelman shower model (Andelman 1985, Andelman 1990). This calculation was necessary to estimate the exposure that would occur due to the volatilization of the TCE during the showering process and the subsequent inhalation of the TCE contaminated air by the resident.

- The average level of TCE detected in the public supply wells from October 17, 2005 to October 17, 2006 was used for the concentration in water (0.201 mg/L).
- The volatile mass transfer coefficient was assumed to be 0.6 (McKone and Knezovich 1991).
- The flow rate in the shower was assumed to be 8 L/min (Maslia, et al, 1996).
- The time in the shower varied by age group and the times used in the equation are listed in Table 3.
- The bathroom volume was assumed to be 10 m^3 (Maslia, et al, 1996).

The results of the calculations in Exhibit 2 provide the peak shower concentration. These results need to be converted to a 24-hour exposure concentration to compare to inhalation guidelines such as EPA's reference concentration (RfC) or a point of departure such as a human equivalent dose or lowest observed adverse effect level. The following calculations are used to accomplish this conversion.

Inhalation Intake

Using TCE at 0.201 mg/L, the following bathroom air concentration is estimated for 21-65 year olds who take a 15 minute shower:

C air max = (0.6) (8 L water/min)(15 min) (0.201 mg/L water) (1,000 L air/m^3) / (10,000 L air)

C air max = 1.4 mg/m^3

Therefore, the concentration of TCE in bathroom air for 21-65 year olds who take a 15-minute shower is estimated to be 1.4 mg/m^3.

Dermal intake converted to an air concentration

In addition to exposure from breathing chemicals, people also absorb these chemicals through their skin while showering and bathing. Using a skin permeability constant, scientists have developed an equation for estimating the amount of chemical that is absorbed through the skin during a shower (Brown et al. 1984). Chemical exposure via skin can be estimated using the following formula:

Skin dose =

(skin permeability constant) (duration of exposure)(total body surface area)(percent of body surface area exposed)(chemical concentration in water)(fraction remaining after volatilization)

The units are (L/cm^2 -- hr) (hr) (cm^2) (%) (mg/L)(%), which cancel out to mg. The permeability constant for chlorinated organic chemicals, like TCE, is assumed to be 0.001 L/cm-hr (Brown et al. 1984) and 40% of the chemical is assumed to remain in the shower water after volatilization (Andelman 1985, McKone 1991). The assumed breathing rate, skin surface area, and shower time vary depending upon age group as displayed in Table 3.

The following example using TCE shows the estimated dose for 21-65 year olds from skin absorption and shows how to convert that estimated dose to an air concentration. First, it is necessary to estimate the skin intake using the previously described equation:

Skin intake, adults = (0.001 L/cm^2--hr)(15/60hr)(19780 cm^2)(1)(0.201 mg/L)(0.4).

Skin intake, adults = 0.40 mg TCE

Next, it is necessary to convert the skin intake of 0.40 mg to an equivalent air concentration that someone would breathe while taking a 15-minute shower.

Air concentration from skin exposure, adults =

Skin intake / inhalation rate x shower duration =

(0.40 mg) / (0.012 m^3/min x 15 minutes) = 0.40/0.18

= 2.2 mg/m^3

Therefore, a concentration of 2.2 mg/m^3 TCE in air breathed for 15 minutes during a shower is equivalent to the estimated skin intake of 0.40 mg from a 15 minutes shower. Converting the skin intake into an air concentration allows both routes of exposure to be summed to provide a combined exposure level.

To estimate the total intake of a specific chemical from bathing in contaminated water, the following exposures need to be considered:

Total intake $_{\text{specific chemical}}$ =

inhalation intake $_{\text{15 minute shower and additional 5 minute bathroom stay}}$

+ skin intake 15 $_{\text{minute shower}}$

+ inhalation intake $_{\text{remainder of the day}}$

The inhalation intake from the remainder of the day is assumed to be zero. Thus, the equation to estimate intake from each pathway is as follows:

(C air max)[1] (breathing rate in m^3/min) (total bathroom time in minutes)

+ (L/cm^2 --hr)(hr)(cm^2)(% surface area)(mg/L)(% not volatilized during shower)

As an example, the total intake for 21-65 year olds from bathing in TCE-contaminated water containing 0.201 mg/L) is:

Total daily intake, 21-65 year olds $_{\text{TCE}}$ =

(1.4 mg/m^3) (0.0124 m^3/min) (20 min)

+ (0.001 L/cm^2-hr)(15/60)(19,780)(1)(0.201 mg/L)(0.4)

Total intake $_{\text{TCE}}$ = 0.35 mg + 0.40 mg = 0.75 mg/day

1 As previously described, C air max in the bathroom = (k) (Fw) (Ts) (Cw) / Va

The next step is to convert the daily intake (in mg) for TCE into a daily (24 hour) air concentration. This 24-hour air concentration becomes a more appropriate number to compare to the point of departures (human equivalent concentration (HEC_{99})) in the studies. To estimate the 24-hour air concentration that is equivalent to a daily intake of 0.75 mg/day involves the following calculation:

24-hour Air Concentration =

(Daily intake $_{TCE}$ in mg) / (average amount of air breathed per day m^3/day)

For 21-65 year olds, the 24-hour Air Concentration of TCE =

(0.75mg/day) / (15.52 m^3/day) = 0.048 mg/m^3

Therefore, for 21-65 year olds, the estimated 24-hour concentration of TCE is 0.048 mg/m^3, and this concentration can be used to compare to points of departure such as the HEC_{99} to determine if harmful effects might occur. The resulting concentrations from conducting these calculations are presented in Table 4 as 24 hour concentrations.

Table 4 ***Calculated Exposure Doses and Inhalation Concentrations used for the Assessment of Noncancer Health Effects from Exposure to TCE in Drinking Water at the Millsboro TCE Site***

	Ingestion	Inhalation	
Age Ranges	**Dose (mg/kg/day)**	**Peak Concentration (mg/m^3)**	**24-hour average Concentration (mg/m^3)**
Birth to <1 year	0.029	NA	NA
1 to <2 years	0.016	NA	NA
2 to <6 years	0.012	1.1	0.026
6 to <11 years	0.0080	1.4	0.045
11 to <21 years	0.0064	1.4	0.045
21 to <65 years	0.0072	1.4	0.048
65+ years	0.0069	0.96	0.032
Pregnant Women (15 to 44 years old)	0.0082	1.4	0.037
NA = Not assessed because infants and toddlers tend to take baths instead of showering and a suitable model does not exist to estimate inhalation exposure while bathing.			

Potential Health Effects from TCE Exposure

Non Cancer Health Effects

EPA's newly issued oral reference dose (RfD) for TCE is 0.0005 mg/kg/day (EPA, 2011c; EPA, 2011d). The RfD is an estimate, with uncertainty factors built in, of the daily, chronic exposure of human populations to a possible hazard that is not likely to cause noncancerous health effects. Of note, a suitable comparison value does not yet exist for the intermediate duration (one year or less) of exposure that was experienced in Millsboro. Therefore, ATSDR compared the estimated exposure doses with effect levels from available studies. EPA based its RfD on three principal toxicological studies:

- Johnson showed increased rates of heart defects in newborn rats born to mothers who were exposed to TCE in drinking water (Johnson *et al.*, 2003). EPA applied Physiologically Based Pharmacokinetic (PBPK) models of TCE metabolism in rats and humans to the study results to obtain a 99^{th} percentile human equivalent dose (HED_{99}) of 0.0051 mg/kg/day. At 0.0051 mg/kg/day ingested TCE, a 1% response rate is expected for fetal heart malformations in humans. Details of the methods used, including PBPK model-based route-to-route extrapolation, are presented in Section 5.1.3 of the Toxicological Review of Trichloroethylene (EPA 2011b).
- A study in female adult mice showed immune system effects (decreased thymus weight) after exposure to TCE in a thirty week drinking water study (Keil *et al.*, 2009). EPA converted the study findings to obtain a HED_{99} of 0.048 mg/kg/day.

- A study in mice exposed from birth to TCE in drinking water showed problems with immune system development (Peden-Adams *et al.*, 2006). EPA used the lowest study effect level of 0.37 mg/kg/day as a point of departure.

Two additional studies were also cited as supporting the RfD:

- Woolhiser *et al.*, (2006) found increased kidney weights (a sign of stressed function) in female rats exposed to TCE by inhalation for four weeks. EPA obtained a HED_{99} of 0.0079 for lifetime continuous exposure.
- NTP (1988) showed kidney effects (toxic nephropathy) in female rats exposed to TCE by gavage for two years. EPA obtained a HED_{99} of 0.0034 for lifetime continuous exposure.

ATSDR compared the above HED_{99} doses with the estimated doses for men, women, and children at the Millsboro site to evaluate the potential for adverse health effects resulting from past exposure:

- Using the 95th % water ingestion rate, all of the age groups exceed, by less than an order of magnitude, the HED_{99} of 0.0051 mg/kg/day for cardiac birth defects. Using the mean water ingestion rate, only the 0 – 2 year old age group exceeds the HED_{99}. Limited epidemiological studies have also shown associations between TCE exposure during pregnancy and birth defects. Therefore, pregnant women who drank unfiltered water may have had an increased likelihood of adverse fetal cardiac effects.
- None of the age groups exceed the HED_{99} of 0.048 mg/kg/day for immune system effects such as decreased weight of the thymus gland) using the 95% water ingestion rate, and none of the estimated doses approach the effect level of 0.37 mg/kg/day for effects on the developing immune system.
- Using the 95% water ingestion rate, all of the age groups exceed, by less than an order of magnitude, the HED_{99} of 0.0034 mg/kg/day for kidney effects. Using the mean water ingestion rate, only the 0 – 6 year old age group exceeds the HED_{99}. This evaluation indicates that children and adults, who drank unfiltered TCE-contaminated water may have had an increased likelihood of adverse effects to their kidneys. TCE exposure can also cause kidney cancer, with increased susceptibility for early-life exposures. The Estimated Cancer Risk section provides more detail.

EPA's newly issued inhalation reference concentration (RfC) for TCE is 0.002 mg/m^3 (EPA, 2011c; EPA, 2011d). The RfC is an estimate, with safety factors built in, of the daily, life-time exposure of human populations to a possible hazard that is not likely to cause noncancerous health effects. Of note, a suitable comparison value does not yet exist for the intermediate duration of exposure that was experienced in Millsboro. Therefore, ATSDR must compare its estimated 24-hour concentrations with effect levels from available studies. EPA based its RfC on two principal toxicological studies:

- Johnson et al. (2003) found increased fetal cardiac malformations in rats that were exposed to TCE in drinking water from gestation day 1 to 22. EPA applied PBPK models to derive route-to-route extrapolation for developmental and immunologic effects to obtain a 99th percentile HEC_{99} of 0.021 mg/m^3. At 0.021 mg/m^3 TCE in air, a 1% response rate is expected for fetal heart malformations in humans. Details of the methods used, including PBPK model-based route-to-route extrapolation, are presented in Section 5.1.3 of the Toxicological Review of Trichloroethylene (EPA 2011b).
- Keil et al. (2009) found decreased thymus weight in female mice that were exposed to TCE in drinking water for 30 weeks. EPA applied PBPK models to derive route-to-route extrapolation for developmental, immunologic, and kidney effects to obtain a 99th percentile human equivalent concentration (HEC_{99}) of 0.19 mg/m^3.

ATSDR compared the preceding HEC_{99} with the estimated 24-hour average concentrations for men, women, and children at the Millsboro site to evaluate the potential for adverse health effects resulting from past exposure while showering:

- The HEC_{99} of 0.19 mg/m^3 was not exceeded by any age group. The HEC_{99} in the Keil study addresses decreased thymus weight. This suggests that there would not have been an increased likelihood of adverse immunological effects as a result of showering.
- The HEC_{99} of 0.021 mg/m^3 was exceeded by all age groups but no age group exceeded the HEC_{99} by more than a factor of 2.5. The HEC_{99} in the Johnson study addresses increased fetal cardiac malformations. This suggests that there may be an increased likelihood of adverse fetal cardiac effects.

Estimated Cancer Risk

The National Toxicology Program (NTP) states that TCE is reasonably anticipated to be a human carcinogen based on limited evidence of carcinogenicity from studies in humans, sufficient evidence of carcinogenicity from studies in experimental animals, and information from studies on mechanisms of carcinogenesis (NTP, 2011). The human studies were epidemiological studies that showed increased rates of liver cancer and non-Hodgkin's lymphoma, primarily in workers who were exposed to TCE on the job. The animal studies showed increased numbers of liver, kidney, testicular, and lung tumors by two different routes of exposure (NTP, 2011). EPA characterizes TCE as carcinogenic to humans by all routes of exposure (EPA, 2011d). This conclusion is based on human epidemiology studies showing associations between human exposure to TCE and kidney cancer, non-Hodgkin's lymphoma, and liver cancer.

The excess cancer risk is the number of increased cases of cancer in a population above background that may result from exposure to a particular contaminant under the assumed exposure conditions from site-related contamination. For example, an estimated cancer risk of 1×10^{-6} represents a possible one excess cancer cases in a population of one million. Because of the uncertainties and conservatism inherent in deriving the cancer slope factors, this is only an estimate of risk; the true risk is unknown (ATSDR 2005b). To help illustrate one excess cancer case in a population of one million it is useful to compare that increased risk to something that we are familiar with. For example, one in one million would be the equivalent of one inch in 16 miles or one minute in two years. This comparison helps illustrate how low a one in one million cancer risk is.

At the publication of ATSDR's draft HC for this site, EPA was reviewing its TCE health risk assessment, and an oral cancer slope factor for TCE was not available in the EPA's IRIS database. In the draft HC, ATSDR followed interim guidance recommending use an oral cancer slope factor developed by the California EPA (Cal-EPA), 0.0059 $(mg/kg/day)^{-1}$, for ingestion and an inhalation unit risk of 2.0×10^{-6} $(\mu g/m^3)^{-1}$ for quantitative evaluation of TCE exposures (CalEPA, 2003). In late September 2011, EPA published a revised IRIS oral cancer slope factor for TCE of 0.046 $(mg/kg/day)^{-1}$ and an inhalation unit risk of 4.1×10^{-6} $(\mu g/m^3)^{-1}$ reflecting total incidence of kidney, non-Hodgkins lymphoma, and liver cancers (EPA, 2011c; EPA, 2011d). The following updated evaluation uses the latest EPA oral cancer slope factor and inhalation unit risk factor to evaluate the potential for increased risk of cancer resulting from past TCE exposures at this site.

EPA used a PBPK model-based route-to-route extrapolation of the inhalation unit risk estimate for kidney cancer, with a factor of 5 applied to include non-Hodgkin's lymphoma and liver cancer risks, to obtain an oral slope factor for combined cancer risk of 4.6×10^{-2} (0.046) $(mg/kg/day)^{-1}$ (EPA, 2011c). The combined cancer slope factor can be split into components as follows: for kidney cancer, the oral slope factor is 9.33×10^{-3} $(mg/kg/day)^{-1}$; for non-Hodgkin's lymphoma, the slope factor is 2.16×10^{-2} $(mg/kg/day)^{-1}$; and for liver cancer, the slope factor is 1.55×10^{-2} $(mg/kg/day)^{-1}$ (EPA, 2011c). Of note,

PBPK modeling is a mathematical modeling technique that is used to predict the movement of chemicals through the body.

EPA also concluded, by a weight of evidence evaluation, that TCE is carcinogenic by a mutagenic mode of action for induction of kidney tumors. As a result, increased early-life susceptibility is assumed for kidney cancer, and age-dependent adjustment factors (ADAFs) should be used for the kidney cancer component of the total cancer risk when estimating age-specific cancer risks. 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 greater than 16).

For a given period of exposure, the component oral cancer slope factor 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. ATSDR calculated the increased cancer risk by assuming a duration of 1 year. For example, consider a child less than 2 years old drinking 0.89 L of water containing 201 µg/L TCE every day. The exposure dose was calculated earlier to be 0.016 mg/kg/day. The increased risk of cancer is calculated as follows:

Increased Cancer Risk =

$0.016\ \text{mg/kg/day} \times 9.33\times10^{-3}\ (\text{mg/kg/day})^{-1} \times 10\ (\text{kidney cancer ADAF})\ /78\ \text{years}$ (kidney cancer)

$+\ 0.016\ \text{mg/kg/day} \times 2.16\times10^{-2}\ (\text{mg/kg/day})^{-1}\ /78\ \text{years}$ (Non-Hodgkin's lymphoma)

$+\ 0.016\ \text{mg/kg/day} \times 1.55\times10^{-2}\ (\text{mg/kg/day})^{-1}\ /78\ \text{years}$ (liver cancer)

$=2.6\times10^{-5}$ = about 3 in 100,000

We assumed as a worst case that exposure lasted for one year. Table 5 below summarizes the estimated increased risks of cancer for potential past exposures for individuals who consumed water at the 95th % ingestion rate while Table 6 summarizes the estimated increased risks of cancer for potential past exposures for individuals who consumed water at the mean ingestion rate. ATSDR calculated the estimated cancer risk and considered exposure from ingestion, inhalation, and dermal absorption from TCE contaminated water. The total estimated cancer risks are also presented in Tables 5 and 6. The risks are presented for each age group considering each route of exposure and the risks are then summed to find the total risk. EPA's general target risk range is 1 in 1,000,000 to 1 in 10,000. The calculated risks range from 3 in 1,000,000 to 5 in 100,000.

Table 5 ***Estimated Increased Risk of Cancer for Past Exposure to TCE in Drinking Water at the Millsboro TCE Site using the 95% Ingestion Rate of Drinking Water***

Increased Risk of Cancer				
Age Range	**Ingestion Cancer Risks**	**Inhalation Cancer Risks**	**Dermal Cancer Risks[1]**	**Total Cancer Risk**
Birth to <1 year	5 in 100,000	NA	NA	5 in 100,000
1 to <2 years	3 in 100,000	NA	NA	3 in 100,000
2 to <6 years	1 in 100,000	4 in 10,000,000	4 in 10,000,000	1 in 100,000
6 to <11 years	7 in 1,000,000	5 in 10,000,000	5 in 10,000,000	8 in 1,000,000
11 to <21 years	5 in 1,000,000	5 in 10,000,000	5 in 10,000,000	6 in 1,000,000
21 to <65 years	4 in 1,000,000	5 in 10,000,000	5 in 10,000,000	5 in 1,000,000
65+ years	4 in 1,000,000	4 in 10,000,000	4 in 10,000,000	5 in 1,000,000
Pregnant women 15 to 44 years	5 in 1,000,000	5 in 10,000,000	5 in 10,000,000	6 in 1,000,000

[1] Note: Dermal cancer risk is conservatively estimated to be equivalent to the inhalation cancer risk (Jo et.al. 1990)

NA = Not assessed because infants and toddlers tend to take baths instead of showering and a suitable model does not exist to estimate inhalation exposure while bathing.

EPA's target risk range for Superfund Sites is 1 in 1,000,000 to 1 in 10,000.

Table 6 *Estimated Increased Risk of Cancer for Past Exposure to TCE in Drinking Water at the Millsboro TCE Site using the Mean Ingestion Rate of Drinking Water*

Increased Risk of Cancer				
Age Range	**Ingestion Cancer Risks**	**Inhalation Cancer Risks**	**Dermal Cancer Risks[1]**	**Total Cancer Risk**
Birth to <1 year	2 in 100,000	NA	NA	2 in 100,000
1 to <2 years	9 in 1,000,000	NA	NA	9 in 1,000,000
2 to <6 years	4 in 1,000,000	4 in 10,000,000	4 in 10,000,000	5 in 1,000,000
6 to <11 years	3 in 1,000,000	5 in 10,000,000	5 in 10,000,000	4 in 1,000,000
11 to <21 years	2 in 1,000,000	5 in 10,000,000	5 in 10,000,000	3 in 1,000,000
21 to <65 years	2 in 1,000,000	5 in 10,000,000	5 in 10,000,000	3 in 1,000,000
65+ years	2 in 1,000,000	4 in 10,000,000	4 in 10,000,000	3 in 1,000,000
Pregnant women 15 to 44 years	2 in 1,000,000	5 in 10,000,000	5 in 10,000,000	3 in 1,000,000

[1] Note: Dermal cancer risk is conservatively estimated to be equivalent to the inhalation cancer risk (Jo et.al. 1990)

NA = Not assessed because infants and toddlers tend to take baths instead of showering and a suitable model does not exist to estimate inhalation exposure while bathing.

EPA's target risk range for Superfund Sites is 1 in 1,000,000 to 1 in 10,000.

Conclusions

Currently, Millsboro's public water supply is not expected to harm people's health. The granulated active carbon treatment system added to the two contaminated water supply wells in 2005 remove TCE. Ongoing sampling efforts confirm TCE levels are below federal drinking water standards, ATSDR health-based guidelines, and the contract required quantitation limit of 0.5 µg/L.

Millsboro residents experienced some level of exposure to TCE from contaminated drinking water beginning sometime between October 18, 2004, and October 17, 2005. Assuming exposure occurred for a year-- based on the average weekly contaminant concentrations from October 17, 2005 to October 17, 2006-- past exposures may have increased the likelihood for adverse noncancer health effects. Since a suitable comparison value does not yet exist for the intermediate duration (one year or less) of exposure that was experienced in Millsboro, ATSDR compared the estimated exposure doses with effect levels from available studies. Regarding exposure from ingestion, ATSDR compared the doses to the HED_{99}, and this evaluation indicated that children and adults who drank unfiltered TCE-contaminated water at this site may have had an increased likelihood of effects to their kidneys and pregnant women might have had an estimated increased risk of adverse fetal cardiac effects. Regarding exposure from inhalation during showering, ATSDR compared the calculated concentrations to the HEC_{99}, and this evaluation indicated that pregnant women exposed to TCE while showering may have had a greater potential of delivering a child with adverse fetal cardiac effects. There is a low level of increased risk for carcinogenic health effects. It is important to note that ATSDR took a conservative approach in its estimations and the actual concentration of TCE that people were exposed to is unknown and were likely less.

Data are inadequate to conclude whether the TCE VI pathway in Millsboro could harm people's health. The information needed to make a decision is not available. ATSDR is working with DNREC-SIRS and EPA to gather the needed information.

Recommendations

- Continue monitoring for TCE in public supply wells to ensure that the water provided to residents is safe.
- Better assess the possibility of vapor intrusion from TCE-contaminated groundwater into homes.
- The Town of Millsboro should take necessary measures to prevent downward migration of TCE contamination into the Manokin Aquifer. Millsboro Water Department should confer with EPA and DNREC to develop operation guidance that will maintain plume control.

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Figures

Figure 1: Millsboro TCE (Millsboro, DE) Site Map and Demographic Characteristics

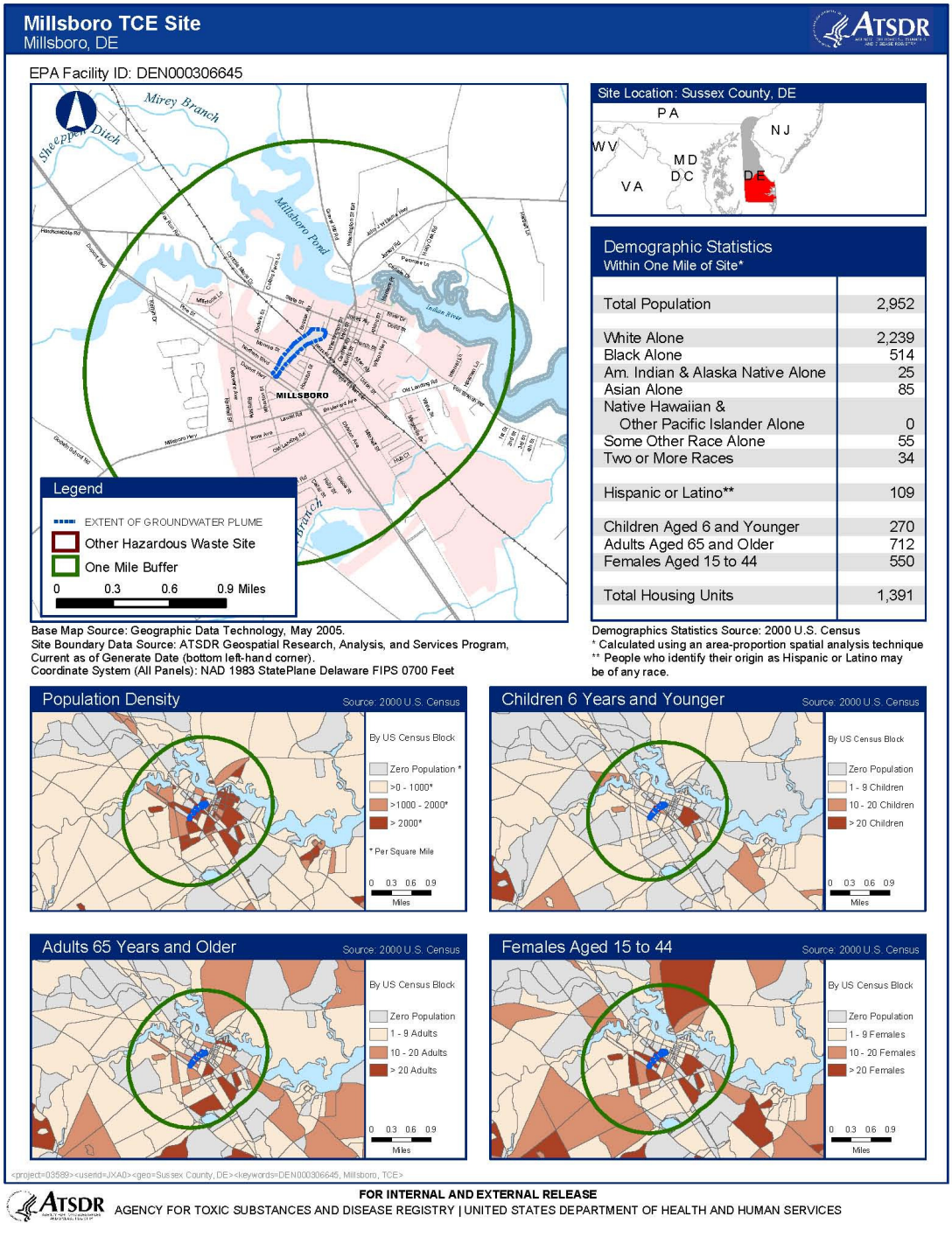
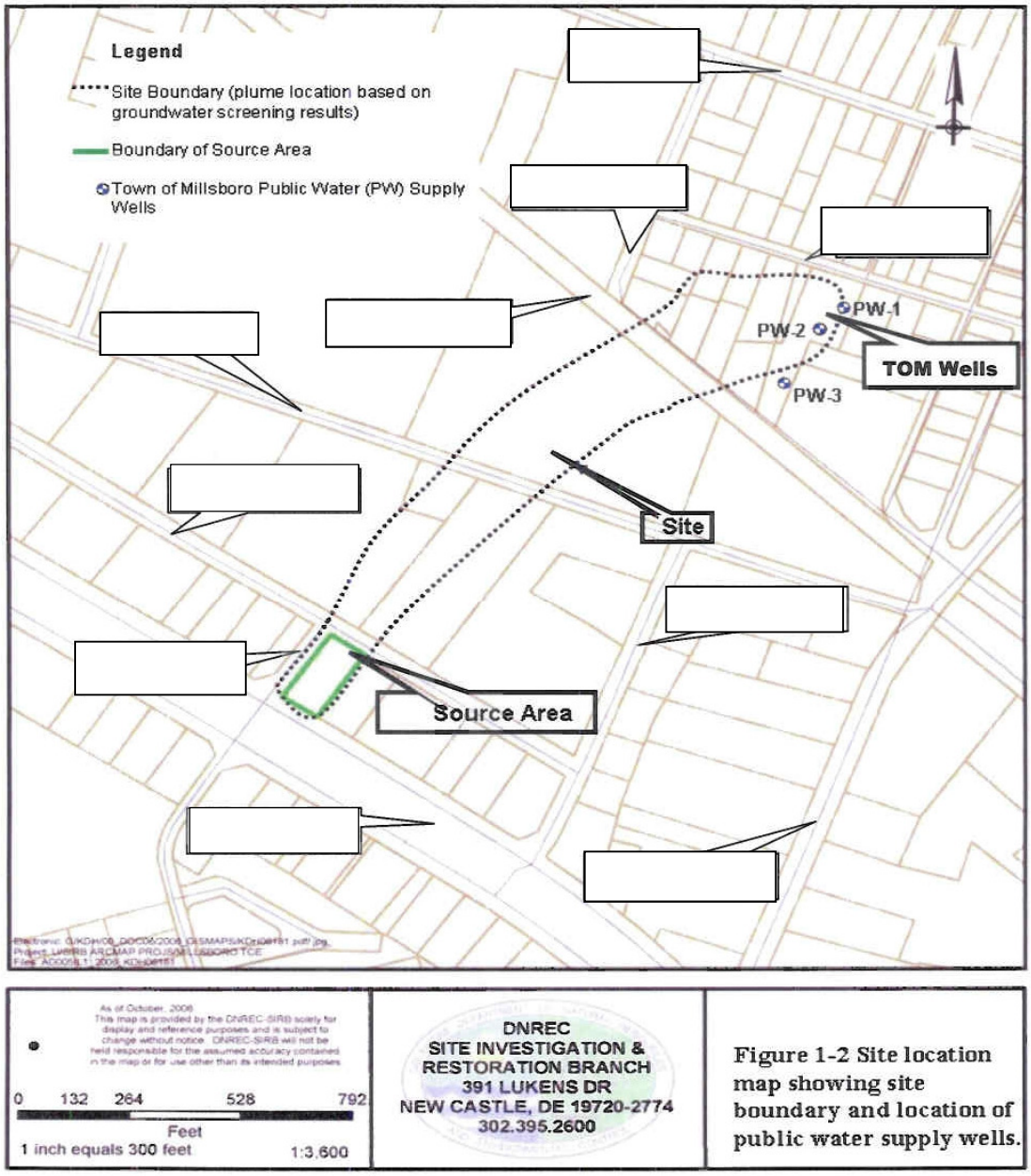


Figure 2: TCE plume map



Source: DNREC. Final Plan of Remedial Action Millsboro TCE Groundwater Contamination Site. DNREC Project No. DE-1361 2007

Of note, street names have been removed.

Figure 3: Granulated Activated Carbon Filtration System

Appendix A

TCE Concentrations of Millsboro Public Supply Wells (µg/L)

	PW-1	PW-2	Concentration after well mixing
10/17/2005	25.1	217	94.3
10/27/2005	91.6	8.15	36.1
11/14/2005	62.2	89.4	57.5
12/13/2005	67	14	30
12/20/2005	110	170	106
12/27/2005	170	110	104
1/24/2006	110	310	161
1/31/2006	140	250	149
2/7/2006	160	270	164
2/14/2006	140	330	180
2/28/2006	110	440	212
3/7/2006	100	520	240
3/14/2006	87	600	267
4/4/2006	57	630	268
4/11/2006	38	630	261
4/18/2006	64	500	220
4/25/2006	140	180	121
5/2/2006	120	570	267
5/9/2006	160	580	285
5/16/2006	140	530	259
5/23/2006	120	650	299
5/30/2006	130	670	310
6/6/2006	120	680	310
6/13/2006	110	730	326
6/27/2006	98	790	346
7/5/2006	91	630	280
7/18/2006	73	510	227
7/25/2006	62	770	325
8/1/2006	40	510	215
8/8/2006	31	470	196
8/15/2006	29	510	211
8/22/2006	21	670	271
8/29/2006	20	530	216
9/5/2006	22	530	216
9/12/2006	20	410	168
9/20/2006	21	440	181
9/26/2006	24	440	182
10/3/2006	20	440	180
10/10/2006	88	NA	31.6
10/17/2006	110	36	53.6
Average TCE concentration taking into account the contribution of each well			**201**

PW-1contributes 260 gpm, PW-2 285 gpm and PW-3 180 gpm or 35.9%, 39.3%, and 24.8%, respectively of the public water supply

NA – Not Analyzed

Data provided by DNREC

Appendix B

ATSDR's Screening Analysis

ATSDR gathers information for the exposure evaluation to gain an understanding of the site and community health concerns, the nature and extent of contamination, and exposure pathways, and begins performing the other scientific component of the public health assessment process—the health effects evaluation. The health effects evaluation consists of two pieces: a screening analysis and, at some sites, based on the results of the screening analysis and community health concerns, a more in-depth analysis to determine possible public health implications of site-specific exposures.

Screening Process

In evaluating these data, ATSDR used 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.

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 noncancer health effects. Noncancer levels are based on valid toxicological studies for a chemical, with appropriate safety factors included, and the assumption that small children (22 pounds) and adults are exposed every day. Cancer levels are based on a one-in-a-million excess cancer risk for an adult exposed to contaminated soil or drinking contaminated water every day for 70 years. For chemicals for which both cancer and noncancer levels 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.

CVs used in preparing this document are listed below:

Environmental Media Evaluation Guides (EMEGs) are estimated contaminant concentrations in a media where noncarcinogenic health effects are unlikely. EMEGs are derived from the Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk level (MRL).

Cancer Risk Evaluation Guides (CREGs) are estimated contaminant concentrations that would be expected to cause no more than one additional excess cancer in one million persons exposed over a lifetime. CREGs are calculated from U.S. Environmental Protection Agency (EPA) cancer slope factors (CSFs).

Reference Media Evaluation Guides (RMEGs) are estimated contaminant concentrations in a media where noncarcinogenic health effects are unlikely. RMEGs are derived from EPA's reference dose (RfD).

Lifetime Health Advisories (LTHAs) are derived by EPA from a drinking water equivalent level below which no adverse noncancer health effects are expected to occur over a 70-year lifetime.

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 (MCLGs, 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.

EPA Regional Screening Levels (RSLs) are risk-based concentrations derived from standardized equations combining exposure information assumptions with EPA toxicity data. EPA considers RSLs to be protective for humans (including sensitive groups) over a lifetime.

Some CVs may be based on different durations of exposure. Acute duration is defined as exposure lasting 14 days or less. Intermediate duration exposure lasts between 15 and 364 days, and chronic exposures last 1 year or more. Comparison values based on chronic exposure studies are used whenever available. If an intermediate or acute comparison value is used, it is denoted with a small *i* or *a* before the CV (e.g., iEMEG refers to the intermediate duration EMEG).

Determination of Exposure Pathways

ATSDR identifies human exposure pathways by examining environmental and human components that might lead to contact with contaminants of concern (COCs). A pathway analysis considers five principal elements: a source of contamination, transport through an environmental medium, a point of exposure, a route of human exposure, and an exposed population. Completed exposure pathways are those for which the five elements are evident, and indicate that exposure to a contaminant has occurred in the past, is now occurring, or will occur in the future. Potential exposure pathways are those for which exposure seems possible, but one or more of the elements is not clearly defined. Potential pathways indicate that exposure to a contaminant could have occurred in the past, could be occurring now, or could occur in the future. The identification of an exposure pathway does not imply that health effects will occur. Exposures might be, or might not be, substantive. Therefore, even if exposure has occurred, is now occurring, or is likely to occur in the future, human health effects might not result.

ATSDR reviewed site history, information on site activities, and the available sampling data. On the basis of this review, ATSDR identified household use of supplied well water as the main pathway of concern at the Millsboro TCE site.

Evaluation of Public Health Implications

The next step is to take those contaminants present at levels above the CVs and further identify which chemicals and exposure situations are likely to be a health hazard. Child and adult exposure doses are calculated for the site-specific exposure scenario, using our assumptions of who goes on the site and how often they contact the site contaminants. The exposure dose is the amount of a contaminant that gets into a person's body. Following is a brief explanation of how we calculated the estimated exposure doses for the site.

Noncancer Health Effects

The calculated exposure doses are then 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 noncancer 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, noncancerous 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.html.

Reference Dose (RfD) —Developed by EPA

An RfD is an estimate, with safety factors built in, of the daily, life-time exposure of human populations to a possible hazard that is not likely to cause noncancerous health effects. RfDs can be found at http://www.epa.gov/iris.

If the estimated exposure dose for a chemical is less than the health guideline value, then the exposure is unlikely to cause a noncarcinogenic 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 toxicologic values for that chemical and is discussed in more detail in the public health assessment (see Discussion section). These toxicologic values are doses derived from human and animal studies that are summarized in the ATSDR *Toxicological Profiles*. 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.

Cancer Health Effects

The estimated risk of developing cancer resulting from exposure to the contaminants was calculated by multiplying the site-specific adult exposure dose by EPA's corresponding CSF (which can be found at http://www.epa.gov/iris). The results estimate the maximum increase in risk of developing cancer after 70 years of exposure to the contaminant. For this site, we assumed 40 years as a conservative worst-case exposure duration, because the neighborhood was not built before the late 1970s. Therefore, the maximum increased cancer risk was multiplied by the factor (40/70) to account for a less-than lifetime exposure.

The actual increased risk of cancer is probably lower than the calculated number, which gives an estimated worst-case excess cancer risk. 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. Lastly, the method computes the upper 95th percent confidence limit for the risk. The actual cancer risk can be lower, perhaps by several orders of magnitude (EPA, 1989).

Because of uncertainties involved in estimating carcinogenic risk, ATSDR employs a weight-of-evidence approach in evaluating all relevant data (ATSDR, 1993). Therefore, the carcinogenic risk is described in words (qualitatively) rather than giving a numerical risk estimate only. The numerical risk estimate 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.

Appendix C

Public Comments

From August 17, 2011 through September 17, 2012, ATSDR released this Millsboro TCE Health Consultation (HC) for public review and comment. This appendix contains both the comments received during the comment period and ATSDR's response to those comments. In addition, text in the HC was modified where required.

Comment 1 - In the absence of conducting a peer review process for the new MRLs, ATSDR should use the MRLs currently available in its Toxicological Profile in performance of an updated Millsboro Health Consultation.

ATSDR Response – It is ATSDR's policy to use the best available science to make health-protective conclusions regarding exposures to contaminants. A thorough review of the derivation of the updated EPA RfD and RfC indicates that the acute and intermediate ATSDR Minimal Risk Levels (MRLs) presented in the ATSDR Toxicological Profile for Trichloroethylene (ATSDR, 1997) are no longer considered to be adequately protective of human health. Therefore, the updated EPA RfD and RfC provide better, more current science that should be used to evaluate chronic and sub-chronic human health exposures to TCE.

Comment 2 - The use of multiple conservative exposure assumptions to estimate risks and hazards from ingestion and inhalation of water leads to the calculation of a reasonable maximum exposure (RME) scenario. The RME scenario is designed to be representative of a worst case condition and is based on exposure assumptions (i.e., water intake, body weight, shower time, exposure frequency) that are a mixture of average and upper end values... Rather, the most conservative values were used for all assumptions. This selection of input values has yielded an assessment that extends well beyond the "highest exposure that can be reasonably anticipated to occur."

ATSDR Response – A conservative approach was used in the analysis of exposure due to the uncertainty associated with the concentration to which the residents were exposed. However, both the 95% and mean ingestion rates were used to assess potential health effects from TCE exposure. Also, the mean shower times and a 24-hour average were used when assessing inhalation exposure. An exposure factor of 1 was used for the ingestion exposure calculations because the residents were exposed throughout the day, seven days a week. Unless site-specific conditions or site-specific knowledge of the contaminant of concern warrant otherwise, it is prudent to use a bioavailability of 100%.

Comment 3 - In the 2012 Health Consultation, ATSDR used an admittedly conservative approach in determining both the period of exposure as well as the concentration of TCE to which an individual could potentially have been exposed. evaluation of TCE concentrations from five alternate timeframes, ranging from the first six months of TCE detections, to a longer timeframe of the first three years of TCE detections (using the same database and flow weighting concentrations as used by ATSDR), yields average TCE concentrations ranging from 105 µg/L to 177 µg/L, with an overall average TCE concentration of approximately 155 µg/L.

ATSDR Response – Even using the lowest proposed alternate concentration of 105 µg/L, ATSDR's conclusions would not have changed. The dose generated using the 105 µg/L and mean drinking water ingestion rate still generates a value that could cause an increased likelihood of kidney effects and adverse fetal cardiac effects.

Comment 4 - Inhalation of Vapors - For the inhalation pathway, ATSDR did not elaborate on the model used to estimate vapor concentrations during showering. Several models are available for evaluating the shower to inhalation pathway that should be reviewed to justify the selection. An analysis shows that the model used by ATSDR may yield concentrations that are up to an order of magnitude higher than would be estimated by other models (i.e., the IHEM-2 workbook model (CPF 2003) based on the Foster and Chrostowski model (2001)).

ATSDR Response – The Andelman shower model is a suitable model to use. However, that model produces a peak shower concentration which was used for the inhalation exposure analysis. Upon further consideration, a 24-hour average would be a more suitable value to compare to EPA's reference concentration (RfC) or human equivalent concentration (HEC_{99}). The appropriate changes were made in the Health Consultation.

Comment 5 – The use of the EPA IRIS studies are called into question particularly the Johnson study.

ATSDR Response –The EPA IRIS Toxicological Review of TCE has undergone several levels of peer review including: agency review, interagency review, public comment, external peer review by EPA's Science Advisory Board in January 2011, and a scientific consultation review in 2006 by the National Academy of Sciences and is accepted by ATSDR as providing the best available science for the evaluation of human health implications from TCE exposures.

Comment 6 – For the evaluation of potential cancer risks, ATSDR used toxicity data based on lifetime exposure and effects for the evaluation of an exposure scenario that was less than one year. There are several concerns with such an approach.

· Unlike the noncancer evaluation, there is no way to adjust the toxicity value (i.e., cancer slope factor) to make it applicable to such short exposure durations. This leaves serious questions as to whether a one year exposure (to environmental levels) is even relevant to cancer risk.

· The cancer risk assessment for TCE is overly conservative because the analysis has not accounted for the possibility of a threshold. In other words, an effect is only seen after a certain amount of exposure to TCE occurs. Several effects, including liver tumors in mice, are likely to be governed by a threshold.

· The major rodent tumor types have been linked to the production of specific TCE metabolites (or breakdown products). However, humans metabolize TCE at a much slower rate and through different pathways than rats and mice, and are expected to produce much lower levels of these chemicals in the body. Indeed, the epidemiological study of TCE with respect to cancer incidence has been extensive, and has not confirmed the findings from rodent studies, but has been characterized by mixed and inconclusive findings (Scott and Jinot, 2011). These data, combined with the understanding of the mechanism of action for rodent carcinogenesis, have been cited as strong evidence that rodent tumors, particularly liver tumors in mice, may not be relevant to humans, and that no TCE-related cancers may be relevant to typical levels of human exposure (reviewed in Delzell et al. 1994; Jollow et al. 2009).

ATSDR Response – Even when using our conservative approach, the increased cancer risk is not elevated to a level that usually warrants concern.

Comment 7 – The revised noncancer evaluation should clarify that the potential for noncancer health effects is extremely limited and exists only in the event that multiple worst-case assumptions are accepted. To clarify this conservatism, we recommend a revision to Conclusion 2.

ATSDR Response – A conservative approach was taken when assessing exposure. However, both 95% and mean values were used in the exposure analysis and when the mean values were used, the doses still exceeded the comparison values in some age groups. Therefore, ATSDR believes our approach is reasonable and protective of public health.

Comment 8 – Data on vapor intrusion have been collected and were provided to EPA at the end of July 2012. Specifically, ARCADIS, on behalf of Mallinckrodt and Intervet, implemented the 2012 Final Phase 1 Project Plan Addendum for Vapor Intrusion Investigations (VI Work Plan) during May and June 2012. This VI Work Plan had been approved by EPA on February 2, 2012.

The Phase 1 work has been completed. These data indicate that no further evaluation of the vapor intrusion pathway is warranted.

ATSDR Response – Once all stakeholders have an opportunity to review and provide comments on the Phase 1 work, ATSDR will consider revising Conclusion 3. To date, only the potentially responsible party's contractor has vetted the Phase 1 report.

Comment 9 – There is concern about using the RfD and RfC as reference levels.

ATSDR Response – The EPA RfD and RfC are defined in terms of chronic daily or continuous exposure that is likely to be without risk of deleterious non-cancer effects during a lifetime. However, critical developmental endpoints involve less-than-lifetime windows of susceptibility that must be considered when evaluating the potential for health impacts. The major milestones for fetal cardiac development in humans occur over a period of approximately 3 weeks. Therefore, it is appropriate to apply the RfD and RfC to pregnant women and women of reproductive age over any three-week period of exposure to consider developmental toxicity.

While EPA and ATSDR do not have finalized health guidelines for the evaluation of intermediate exposures (occurring 15-364 days), the EPA RfD and RfC were developed (in part) using rodent studies of intermediate exposure durations. These studies provide useful toxicological information that supports the application of the EPA RfD and RfC for intermediate exposures.

- Johnson et al. (2003) - Fetal heart malformations were observed among rats exposed to TCE during gestation (gestational day 1 to 22).
    - One of three critical studies selected as the basis for the RfD
    - One of two critical studies selected as the basis for the RfC

- Peden-Adams et al. (2006) - Developmental immunological effects were observed among mice exposed to TCE during gestation and for short durations following their birth (gestational day 0 to 8 weeks of age).
    - One of three critical studies selected as the basis for the RfD

- Keil et al. (2009) - Decreased thymus weight in female $B6C3F_1$ mice exposed for 30 weeks by drinking water.
    - One of three critical studies used to develop the RfD
    - One of two critical studies selected as the basis for the RfC

- Woolhiser et al. (2006) - Increased kidney weight in female Sprague-Dawley rats exposed for 4 weeks by inhalation (6 hours/day, 5 days/week).
    - One of the studies used to support the RfD

New Epidemiological Study to Support the Cardiac Malformation Toxicological Endpoint for TCE Exposure

- Forand et al., April (2012) - A study of residents in Endicott, NY, conducted by the New York State Department of Health, reported that maternal exposure to TCE via vapor intrusion was associated with adverse birth outcomes, including fetal cardiac malformations

Comment 10 – The Federal limit for TCE of 5 ppb is not protective of public health.

ATSDR Response – Since the filtration system was installed, the Millsboro water supply has not even exceeded ATSDR's conservative Cancer Risk Evaluation Guide for TCE which is 0.76 ppb. The water currently supplied to residents does not contain levels of TCE that are of concern. The vast majority of the samples do not detect TCE in the water supplied to residents.

Millsboro TCE Site

Millsboro, Delaware
Health Consultation Findings

Site Background

The Millsboro Trichloroethylene (TCE) site is located at 225 West DuPont Highway in Millsboro (Sussex County), Delaware. The site was once a plant that made vaccines for poultry. The plant was torn down in 1999.

The plant used TCE. Waste TCE was found in underground tanks and in the on-site septic system. Sometime between October 2004 and October 2005, TCE contaminated two of the three public water supply wells in the Town of Millsboro. The Town of Millsboro is now filtering the groundwater through activated carbon which removes TCE.

To make sure the carbon treatment removes all the TCE, the Town of Millsboro tests the water every week.

Q. What is ATSDR currently doing at the Millsboro TCE site?

A. The Agency for Toxic Substances and Disease Registry (ATSDR) released a report that looked at the contaminated water to see if health problems might occur from exposure to TCE. This fact sheet summarizes ATSDR's findings. ATSDR will continue to work with the U.S. Environmental Protection Agency (USEPA), the Delaware Department of Natural Resources and Environmental Control (DNREC), and the Town of Millsboro on public health issues related to exposure to TCE from the site.

Q. What has ATSDR done at the Millsboro TCE site?

A. ATSDR met with community members to hear their concerns about the site. The team also met with community leaders. ATSDR reviewed the public well water test results and toured the Millsboro Public Water Facility to see the filtration process.

Q. What did ATSDR find?

A. ATSDR reached three conclusions about the Millsboro TCE site:

1. Millsboro residents were exposed to TCE contaminated water beginning sometime between October 18, 2004, and October 17, 2005. Based on the levels of TCE in the water and the short period of exposure, ATSDR believes there may have been an increased likelihood of certain health effects.

Continued

2. Filters in Millsboro's public water supply have lowered TCE levels below drinking water standards. The current TCE levels in the drinking water are not expected to cause harm to anyone who uses that water for drinking, bathing, cooking, and/or gardening.

3. We do not know yet if TCE vapors might be getting into houses located over the ground water plume. ATSDR continues to work with EPA and the state to find out more about this possibility.

Q. Does TCE cause cancer?

A. TCE may cause cancer. But whether a person will actually get cancer from TCE depends on a number of things:

- How a person came into contact with TCE (air, drinking water, etc.)
- How much and how often they came in contact with TCE
- Other health-related factors

But based on what we know, ATSDR does not expect Millsboro residents to develop cancer because of past TCE contamination of the public water supply.

Q. Are the water, soil, and air in Millsboro safe?

A. The water that is provided by the Millsboro Water Treatment Facility is not expected to cause harm. The water filtration system installed by the Town of Millsboro effectively removes the TCE.

Two investigations have been conducted to see if TCE vapors are at entering homes. Neither found TCE at levels of concern. However, public health officials believe that further investigation is needed.

Q. What were ATSDR's recommendations?

A. ATSDR made three recommendations for the Millsboro TCE site:

1. Continue testing the two public water supply wells, before, during and after filtration. This will ensure that the drinking water does not have levels of TCE that could harm anyone's health.

2. Test soil gas and/or indoor air for TCE in houses located above the contaminated ground water. ATSDR is working with DNREC-SIRB and EPA to gather the needed information.

3. Prevent uncontrolled spread of TCE contamination in the groundwater. The Town of Millsboro and the Millsboro Water Department should continue to work with U.S. EPA and DNREC to prevent the spread of TCE contamination.

Where can I get more information?

If you have any questions, please call us toll free at **1-800-CDC-INFO** or **1-800-232-4636** and ask for information on the Millsboro TCE site. Information can also be found at www.atsdr.cdc.gov