Public Health Assessment for

Exposure to Chlorinated VOCs in Municipal Drinking Water System
San Germán Ground Water Contamination NPL Site
San Germán, Puerto Rico
EPA FACILITY ID: PRN000205957
AUGUST 3, 2012

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Agency for Toxic Substances and Disease Registry

THE ATSDR PUBLIC HEALTH ASSESSMENT: A NOTE OF EXPLANATION

This Public Health Assessment was prepared by ATSDR pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) section 104 (i)(6) (42 U.S.C. 9604 (i)(6)), and in accordance with our implementing regulations (42 C.F.R. Part 90). In preparing this document, ATSDR has collected relevant health data, environmental data, and community health concerns from the Environmental Protection Agency (EPA), state and local health and environmental agencies, the community, and potentially responsible parties, where appropriate.

In addition, this document has previously been provided to EPA and the affected states in an initial release, as required by CERCLA section 104 (i)(6)(H) for their information and review. The revised document was released for a 0-day public comment period. Subsequent to the public comment period, ATSDR addressed all public comments and revised or appended the document as appropriate. The public health assessment has now been reissued. This concludes the public health assessment process for this site, unless additional information is obtained by ATSDR which, in the agency's opinion, indicates a need to revise or append the conclusions previously issued.

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PUBLIC HEALTH ASSESSMENT

Exposure to Chlorinated VOCs in Municipal Drinking Water System
San Germán Ground Water Contamination NPL Site
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EPA FACILITY ID: PRN000205957

Prepared by:

Eastern Branch
Division of Community Health Investigations
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Summary

Introduction

The Agency for Toxic Substances and Disease Registry's (ATSDR) top priority is to ensure that the people living in San Germán, Puerto Rico have the best information possible to safeguard their health.

Man-made chemicals called volatile organic compounds (VOCs), were detected at low levels in municipal drinking water supply wells from 1999-2006. In 2006, the levels exceeded drinking water standards and the wells were shut down. The U.S. Environmental Protection Agency (EPA) has added the San Germán Ground Water Contamination site to the National Priorities List (NPL, or "Superfund"). ATSDR is required to conduct public health activities on all sites proposed for the NPL. EPA is working with the Puerto Rico Environmental Quality Board (EQB) to continue investigating the site.

The purpose of this Public Health Assessment (PHA) is to determine whether the community was harmed by exposure to VOCs in municipal well water and what public health actions need to be taken to reduce harmful exposures. Because of limited available data, ATSDR focused its evaluation on exposure to VOCs in municipal well water. Other potential exposure pathways may be evaluated as more data are collected from the site.

Conclusions

ATSDR reached three important conclusions in the PHA:

Conclusion 1

Today, no exposures to VOCs in drinking water from the former municipal wells at the San Germán Ground Water Contamination site are occurring.

Basis for Conclusion

The affected wells have been shut down or inactive since mid-2006. Water from these wells is not available.

Conclusion 2

Past exposures to VOCs from drinking or using water from the affected wells were below levels likely to cause harm.

Basis for Conclusion

Estimated exposures for VOCs measured in municipal water from late 1999 to 2006 were below levels associated with any adverse health effects, even if people were exposed every day to the highest concentrations measured.

Conclusion 3

More information is needed to assess other potential exposure pathways including vapor intrusion, private wells in the area, and exposure nearer to the source of contamination.

Basis for Conclusion

The source and extent of the contamination has not been identified to date. VOC levels might be higher near source areas and in any area between the source and the affected wells, increasing the potential for exposure.

Next Steps

- EPA and/or EQB should continue efforts to identify the source, characterize the extent of the contamination, and implement remedial measures to address and prevent groundwater contamination.
- ATSDR will evaluate additional data collected by EPA and update the findings of this PHA, if necessary.

For More Information

For further information about this public health assessment, please call ATSDR at 1-800-CDC-INFO and ask for information about the "San Germán Ground Water Contamination Site." If you have concerns about your health, you should contact your health care provider.

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List of Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
Cal-EPA	California Environmental Protection Agency
CREG	Cancer Risk Evaluation Guide
CV	Comparison Value
cis-1,2-DCE	cis-1,2-Dichloroethylene
EPA	U.S. Environmental Protection Agency
EQB	Puerto Rico Environmental Quality Board
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Assessment System
MCL	Maximum Contaminant Level
mg/L	Milligram per liter
MRL	Minimal Risk Level
NPL	National Priorities List
OSHA	Occupational Safety and Health Administration
PCE	Tetrachloroethylene (or Perchloroethylene)
PHA	Public Health Assessment
PRASA	Puerto Rico Aqueduct and Sewer Authority
PRDOH	Puerto Rico Department of Health
RfD	Reference Dose
RMEG	Reference Media Evaluation Guide
TCE	Trichloroethylene (or Trichloroethene)
µg/L	Microgram per liter
VOC	Volatile Organic Compound

Purpose and Health Issues

The San Germán Ground Water Contamination site was proposed for the National Priorities List (NPL) on September 19, 2007 and listed on March 19, 2008. The Agency for Toxic Substances and Disease Registry (ATSDR) is required by Congress to conduct public health activities on all sites proposed for the NPL. This public health assessment evaluates the public health significance of the San Germán Ground Water Contamination site. ATSDR reviewed available environmental data, potential exposure scenarios, and community health concerns to determine whether adverse health effects are possible. Because of limited data, the health risk evaluation focuses only on potential exposures to chlorinated volatile organic compounds (VOCs) in the public drinking water supply. We also raise the possibility that adverse health effects might result from other types of exposure and make recommendations for further sampling that would allow evaluation of such exposures.

Public Comment

ATSDR released a draft of this PHA for public comment on January 17, 2012. The PHA was available for public review and comment at the Biblioteca Pública in San German, Puerto Rico. The document was also available for viewing or downloading from the ATSDR web site. The public comment period was open from January 17, 2012 through April 16, 2012. The public comment period was announced to local media outlets.

No public comments were received on the PHA. This final PHA includes minor updates to toxicological information available since the public comment release. The conclusions and recommendations are unchanged.

Background

Site Description and History

This background information is from site documents [1-4]. The San Germán Ground Water Contamination site ("the site") consists of an area of groundwater in San Germán, Puerto Rico contaminated with chlorinated volatile organic compounds (VOCs). The contamination was identified through routine monitoring of municipal drinking water wells; the source of the groundwater contamination has not been identified at the time of this report. These contaminants are commonly associated with activities such as degreasing, industrial cleaning, and dry cleaning.

The San Germán Urbano public water system is maintained by the Puerto Rico Aqueduct and Sewer Authority (PRASA) and consists of two surface water intakes and seven wells serving a population of about 23,000 people. A sub-system of three interconnected wells (named Retiro, Lola Rodriguez de Tio I—"Lola I", and Lola Rodriguez de Tio II—"Lola II") served about 800 connections. The general well location area is shown in Figure 1. In annual testing taking place in the fourth quarter of 1999, the VOC tetrachloroethylene (PCE) was detected at 2.0 micrograms per liter (μg/L) in the Retiro well; after this, quarterly monitoring of the wells was conducted [2]. Each of the wells had some detections of PCE and/or cis-1,2-dichloroethylene (cis-1,2-DCE), a related VOC, in quarterly water testing. In late 2005, the levels of PCE in the Retiro well exceeded the EPA maximum contaminant level (MCL) of 5 μg/L set for drinking

water. This contamination was reaching water customers because PCE was also detected in samples collected from commercial and residential drinking water taps supplied by the well system; some concentrations exceeded the MCL [5]. The Puerto Rico Department of Health (PRDOH) ordered the Retiro well to be shut down. The well was taken out of service in January 2006 and the pump was removed in February 2006. By July 2006, the Lola I and Lola II wells were not pumping for distribution due to mechanical issues; the wells have been inactive since that time. However, sampling conducted by EPA later in 2006 showed that PCE, cis-1,2-DCE, and another VOC, trichloroethylene (TCE) were still present in the inactive wells.

EPA and the Puerto Rico Environmental Quality Board (EQB) are currently conducting investigations at the site to identify potential sources and to characterize the nature and extent of groundwater contamination. Some potential source areas have been identified and preliminarily sampled; however, the source of the groundwater contamination has not been confirmed at this time. Not enough information exists to fully assess possible health impacts from all the ways exposure might occur ("exposure pathways"). *Therefore, this public health assessment focuses on community exposures to the VOCs present in municipal water before the affected wells were shut down.* This document also recommends appropriate sampling that will allow evaluation of other potentially important exposure pathways.

Demographics

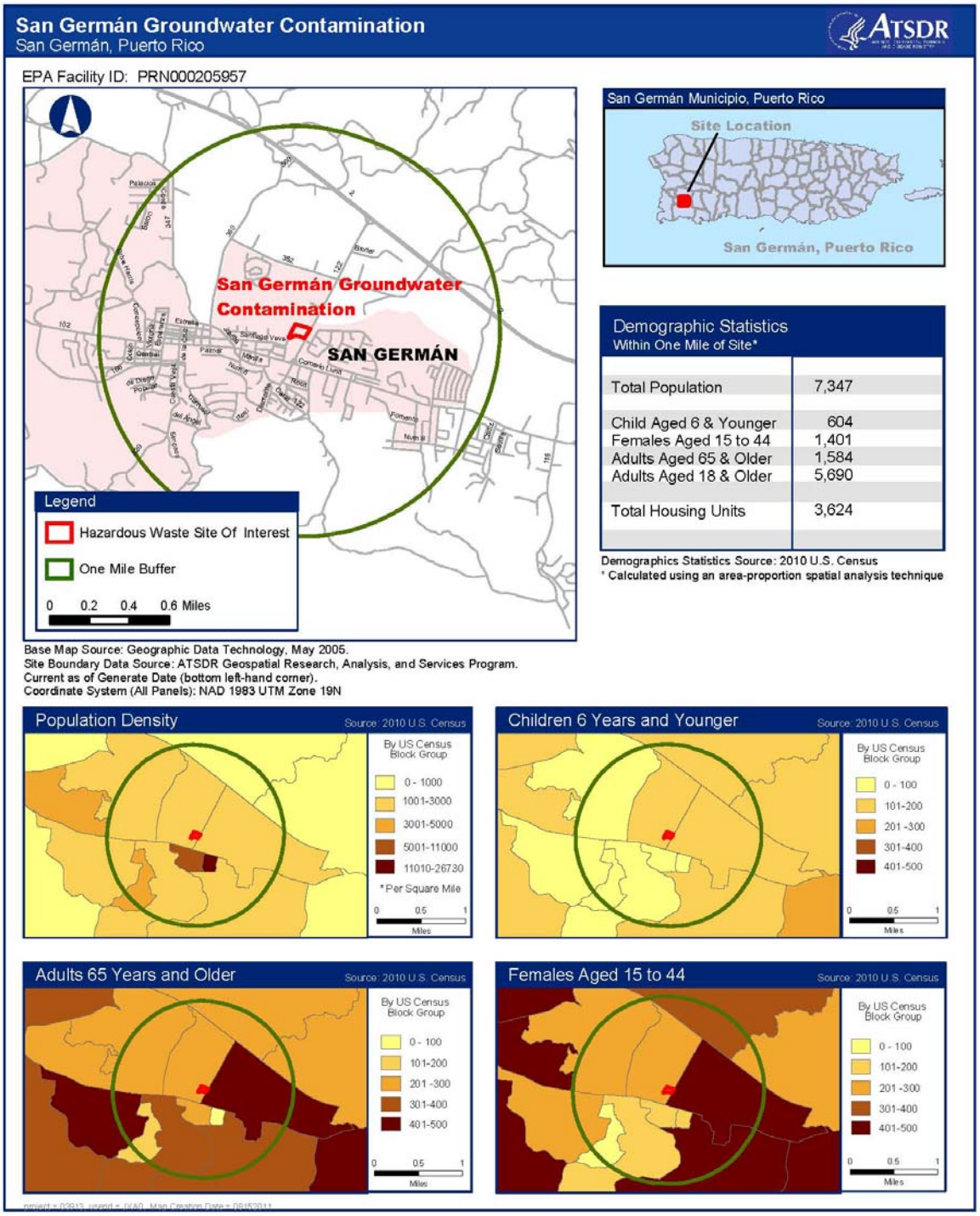
Figure 1 shows demographic information for a 1-mile radius around the affected drinking water wells. The total population living within a one-mile radius of the affected wells is 7,347. Essentially all of the population is of Hispanic or Latino origin. The population living around the affected wells includes the following potentially sensitive groups: about 19% women of childbearing age; about 8% children aged 6 and younger; and about 22% adults aged 65 and older.

Land and Natural Resource Use

The site is a mixed residential, commercial, and industrial area. The three affected public supply wells are located south of and very near the Guanajibo River. The wells are located very close to developed portions of the town but generally in between the town and the river. There is also development, including some large industrial operations and a retirement home, on the north side of the river.

According to a December 2006 report, there were no privately owned wells for domestic use or for agricultural use in the area of the closed PRASA wells [7]. According to EPA officials, the retirement community north of the river has a private well used for drinking water. The water from this well was reportedly tested and found to be free of the contaminants found in the three affected municipal wells [personal communication, Carlos O'Neill, EPA, April 2008]. The fact that this private well is on the opposite side of the Guanajibo River from the affected municipal wells makes it unlikely that they would exhibit similar contamination, because groundwater would tend to flow toward the river from both sides.

Figure 1. Site Map and Demographic Information for the San Germán Ground Water Contamination Site



Groundwater is reported to flow in two ways in the area of San Germán. Topsoil underlain with silt, sand and gravel makes up an overburden area, in which groundwater flow is expected to generally follow topographic features and toward the Guanajibo River [1]. The overburden lies atop bedrock consisting of highly fractured volcanic tuffaceous breccia and conglomerate and cemented limestone. Groundwater flow in the bedrock occurs in fractures and joints between rock types and is much less predictable than the overburden flow [personal communication, Carlos O'Neill, EPA, April 2008]. The affected public supply wells are reported to be screened in bedrock.

According to site documents, the three-well system of Retiro, Lola I, and Lola II served approximately 800 connections.

Discussion

Data Used

The major source of data evaluated in this report is the hazard ranking system (HRS) documentation package; references listed in the package were provided by EPA Region 2 and Puerto Rico authorities [1]. Additional well sampling data was provided by PRDOH [2]. Data evaluated included:

- Results of municipal well sampling by PRASA, PRDOH, and EPA for dates ranging from 1999 to 2006 [2-4];
- Results of tap water sampling by PRDOH in 2006 [5]; and
- Results of groundwater and soil sampling at potential source areas by EPA in 2006 and 2007 [8-13].

ATSDR visited the site[1] to better understand the physical setting of the site and its relationship to the people living and working nearby. During the site visit, the following observations were made:

- The Lola I well was located close to a school with heavy pedestrian traffic. Access to the well and facilities was restricted with a fence and locked gate.
- The Lola II well was also fenced and gated, and the well was located in a relatively isolated area off the main thoroughfare. Pump equipment was overgrown with vegetation.
- The Retiro well was also fenced and gated, and it was located in a relatively isolated area. Although some equipment (overgrown with vegetation) was present, the well casing had been removed and the well plugged.
- The site team also observed the exteriors of two facilities described by EPA as potential source areas (other potential source areas were not specifically observed; EPA has not determined responsibility of any of the potential source areas):

[1]ATSDR Staff (Jill Dyken, Leah Graziano, and Maria Teran-Maciver) visited the site on April 15, 2008 accompanied by the EPA remedial project manager (Carlos O'Neill) and several representatives of EPA, and Puerto Rico authorities including PRASA, EQB, Departamento de Recursos Naturales y Ambientales, and PRDOH.

  - The Wallace International flatware company is an operating manufacturing facility approximately ½ mile east-southeast of the affected wells. The company is located in an industrial park; adjoining properties were mostly commercial/industrial, although there was one home located on the hill on the south side of the property.
  - The PCB Horizon facility is an abandoned facility approximately ½ mile northwest of the affected wells. This is a large facility with several structures, and drums and equipment were present. The facility was fenced and gated, and surrounding properties were solely industrial/commercial.
- Homes in the town appeared to have open windows and other ventilation features. EPA officials stated that homes in the area do not generally have basements or crawl spaces.

Evaluation Process

The typical process by which ATSDR evaluates the potential for adverse health effects to result from exposure to site contaminants will be described briefly in this section.

- When presented with results of comprehensive environmental sampling for chemicals, ATSDR reduces the number of contaminants that need to be evaluated by screening the results for each chemical against *comparison values* (CVs)—concentrations of chemicals in the environment (air, water, or soil) below which no adverse human health effects would be expected to occur. If a contaminant is present at a level higher than the corresponding CV, it does not mean that adverse health effects will occur; the contaminant is merely retained for the next step of evaluation.
- The next step of evaluation focuses on identifying which chemicals and exposure situations could be a health hazard. We calculate *exposure doses*—estimated amounts of a contaminant that people come in contact with and get into their bodies, on an equivalent body weight basis—under specified exposure situations, typically starting with "worst case" type assumptions to obtain the highest dose that could be expected. Each calculated exposure dose is compared against the corresponding *health guideline*, typically an ATSDR minimal risk level (MRL) or EPA Reference Dose (RfD), for that chemical. Health guidelines are considered safe doses; that is, if the calculated dose is at or below the health guideline, no adverse health effects would be expected.
- If the "worst case" exposure dose for a chemical is greater than the health guideline, then the exposure dose may be refined to more closely reflect actual exposures that occurred or are occurring at the site. The exposure dose is then compared to known health effect levels (for both cancer and non-cancer effects) identified in ATSDR's toxicological profiles. *These comparisons are the basis for stating whether or not the exposure presents a health hazard.*

Table 1 summarizes the PRASA monitoring data for the Retiro, Lola I, and Lola II wells in San Germán along with corresponding CVs as discussed above. The available data indicate that only PCE exceeded its CV and warrants further evaluation in this PHA. Since the release of the draft of this PHA for public comment, EPA revised its IRIS oral cancer slope factor for PCE. We have updated the evaluation using the revised oral cancer slope factor.

Table 1. VOCs Detected in San Germán Public Wells Retiro, Lola I, and Lola II

Contaminant	Highest Concentration Detected in Any Well Sample, μg/L	Non-cancer CV in μg/L	Cancer CV in μg/L; Cancer Class	Selected for Further Evaluation? †
PCE	9	5 – MCL	17 – CREG; Probable carcinogen	**Yes**
cis-1,2-DCE	1	20 - RMEG	N/A**	No
TCE	0.5	5 – MCL	0.76 – CREG; Probable carcinogen	No

* Please see Appendix A for definitions and additional information about CVs.
CV = comparison value μg/L = micrograms of contaminant per liter of water
MCL = maximum contaminant level RMEG = reference media evaluation guide
CREG = cancer risk evaluation guide
Data sources: as summarized in "Data Used" section beginning on page 4.
**N/A = insufficient evidence to classify contaminant as oral human carcinogen.
† Contaminants exceeding the lowest CV were selected for further evaluation.

Evaluation of Exposure from Municipal Water

This exposure pathway does not exist today because none of the affected wells have been supplying drinking water since mid-2006 at the latest. However, people could have been exposed in the past beginning in late 1999, when VOCs were first detected in the Retiro well, up until the distribution of water from the contaminated wells ceased in 2006. People could have been exposed to these compounds in several ways:

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

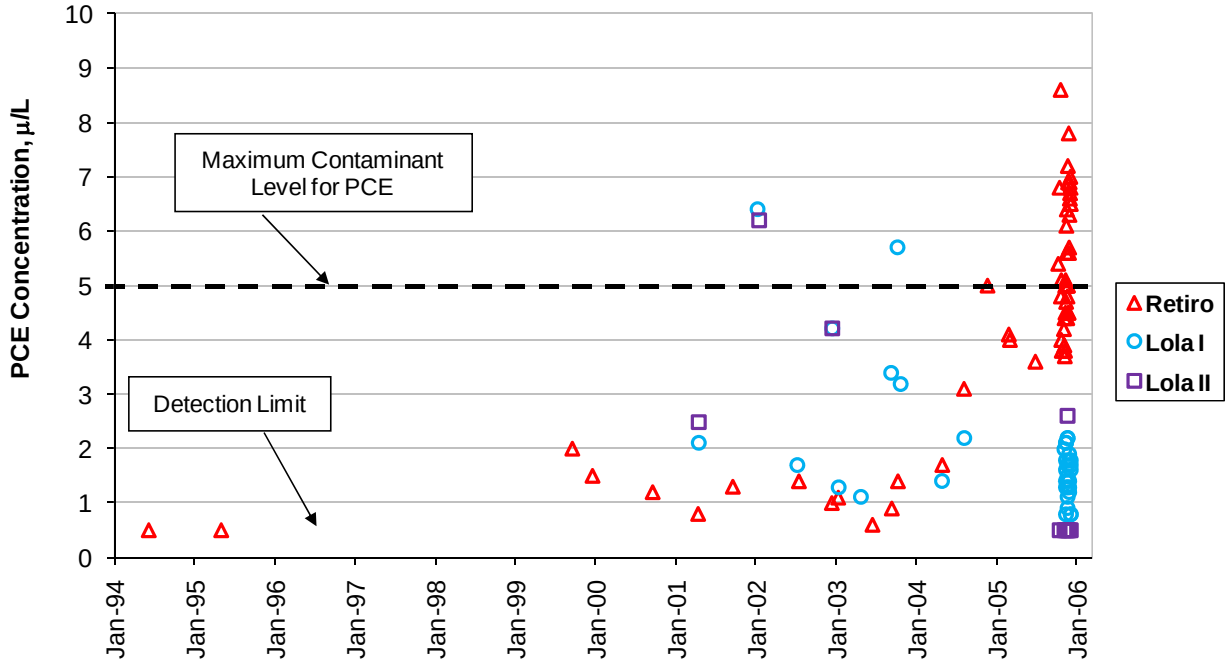
Often, ingestion exposure is the most significant source of exposure to hazardous substances from a site. In the case of VOC contamination, however, inhalation and dermal exposures can make a significant contribution to the total exposure dose (that is, the total amount of contaminant that enters a person's body). A common estimation is that non-ingestion exposures yield a contaminant dose comparable to the ingestion dose [14]. This estimation may underestimate exposures to people who may be exposed to PCE from shower water for periods of 30 minutes or more per day. However, for the general purposes of this evaluation, we doubled ingestion exposure doses estimated using measured water VOC concentrations and default assumptions for the amount of water consumed per day and other exposure parameters to account for additional exposure from inhalation and dermal exposures.

PCE was detected in all three of the wells. Figure 2 shows the PCE results for historical municipal testing of the wells. In late 2005, when the Retiro well's PCE concentration

consistently began to exceed the MCL, residential tap water samples were collected. In several locations, the concentration of PCE in the tap water was as high as in the wells. This confirms that people were being exposed [5]. Before this, however, there were occasional instances of the Lola I and Lola II wells exceeding the MCL for PCE. We do not know the exact levels of PCE people were exposed to at these times because no testing at the tap was performed. The exposure to PCE from the Retiro well stopped in January 2006 when the well was shut down; the Lola I and Lola II wells were discontinued from use as well in mid-2006. To be conservative, in the evaluation performed herein we assume people could have been exposed to PCE for about 7 years – from late 1999, when PCE was first detected in any well, until mid-2006, when use of all three wells stopped.

Because the data indicate slowly increasing contaminant levels in the wells over time, it is unlikely that people were exposed to the highest levels of PCE for the entire time of consideration. However, in order to get a "worst case" estimate of potential exposure dose, we assumed that people were exposed to the highest concentrations of PCE ever measured in the wells every day for the entire 7-year period possible. The concentration used was 9 µg/L PCE.

Figure 2. San German Municipal Wells - Historical Monitoring Results*



*Note: Retiro well was ordered shut by PRDOH in January 2006. Use of the Lola I and Lola II wells was also stopped by mid-2006.

Past Exposure to PCE

Tetrachloroethylene (PCE) is also known as perchloroethylene. It is a solvent that has been used widely in industries for degreasing, dry cleaning, and other similar uses [15].

An estimate of the "worst case" exposure experienced by people from the municipal well system is made assuming people were exposed every day to the highest concentration of PCE measured

(9 µg/L, or 0.009 milligram per liter, mg/L). Exposure dose is further estimated for a one-year-old child weighing 10 kilograms (kg, or 22 pounds). Based on body weight, adults would receive lower exposure doses. Assuming a child drinks one liter of water containing the highest concentration of PCE per day, and multiplying this dose by a factor of 2 to account for non-ingestion exposures, the daily dose of PCE is estimated as

$$Dose = 2 \times \frac{0.009\frac{mg}{L} \times 1\frac{L}{day}}{10\ kg} = 0.0018\, mg\,/\,kg\,/\,day$$

This dose is lower than EPA's RfD for chronic oral exposure to PCE of 0.01 mg/kg/day [16]. Therefore, no non-cancer effects would be expected for this exposure.

The Department of Health and Human Services, National Toxicology Program classifies PCE as reasonably anticipated to be a human carcinogen, and the International Agency for Research on Cancer (IARC) has determined that PCE is a probable human carcinogen. These determinations are based on limited human epidemiological studies suggesting elevated risks for esophageal cancer, non-Hodgkin's lymphoma, and cervical cancer and sufficient animal studies showing that PCE induced leukemia in rats and liver cancers in mice [17,18]. The Environmental Protection Agency considers PCE a likely human carcinogen based on epidemiological evidence showing associations between PCE and bladder cancer, non-Hodgkin's lymphoma, and multiple myeloma [16].

EPA released its updated PCE health risk assessment in February 2012. The oral cancer slope factor was determined to be 0.0021 $(mg/kg/day)^{-1}$. Using this value, and assuming a young child drank water containing the highest concentration of PCE detected in the wells every day for 7 years, there would be an extremely low theoretical increased risk of cancer predicted for this exposure. Fewer than one in one million children drinking the water for 7 years might develop cancer due to exposure to the PCE in the drinking water. Please see Appendix A for details of the cancer risk calculation.

Potential Exposure Pathways

Vapor Intrusion

If VOC levels are high enough in groundwater and the groundwater is close enough to the surface, sometimes VOCs can move through the soil above the water table and/or through cracks or gaps in the subsurface. If the travel pathway leads to a building's interior through a basement, crawl space, or cracks in the foundation, it is possible for the contaminant to build up inside. This is known as *vapor intrusion*, and in some cases vapors from contaminants can reach levels of health concern. EPA recommends evaluating the potential for vapor intrusion at sites where volatile substances are suspected to be present in soil or groundwater at 100 ft of depth or less near existing or future buildings [20]. Stopping or preventing vapor intrusion may involve techniques such as sealing foundation cracks or improving ventilation of the homes to allow vapors to dissipate.

At this point, we don't know if vapor intrusion is a potential problem for homes in San Germán. The levels of VOCs that were present in the municipal wells were too low to cause a concern for

vapor intrusion. However, the source of the contamination has not been determined. Contamination levels could be much higher near the source. Limited sampling performed at one potential source area showed VOC levels in near-surface groundwater thousands of times greater than those detected in municipal wells [8,9]. ATSDR will work with EPA and EQB to ensure that proper characterization of groundwater and soil gas contaminant levels is conducted so that evaluation of this potential exposure pathway can occur.

Incidental Exposure to Surface Soil or Surface Water
Because the source of contamination has not been identified, we do not know conditions of source areas or how people living, working, or playing on or around them might come in contact with any possible contaminants on those sites. There is no indication that soil or surface water near the closed municipal wells are contaminated or would pose a hazard to people nearby. The limited soil sampling available from potential source areas did not indicate any contaminant levels that would be a concern for people living nearby [8-13]. ATSDR will continue to evaluate the potential for exposure to contaminated soil, water, or other identified substances as this information develops throughout the remedial investigation process.

Physical Hazards

No unusual physical hazards were identified in the vicinity of the affected wells. People would not be able to access the well pump houses or associated equipment because they were all fenced with locked gates.

Children's Health Considerations

ATSDR recognizes that infants and children might be more vulnerable than adults to exposures in communities with contaminated air, water, soil, or food. This potential vulnerability results from the following factors: 1) children are more likely to play outdoors and bring food into contaminated areas; 2) children are shorter and therefore more likely to contact dust and soil; 3) children's small size results in higher doses of chemical exposure per kg of body weight; and 4) developing body systems can sustain permanent damage if toxic exposures occur during critical growth stages. Because children depend completely on adults for risk identification and management decisions, ATSDR is committed to evaluating their special interests at the site.

Because small children were potentially exposed to contaminated municipal water before the wells were taken out of service, ATSDR estimated exposures conservatively, using exposure assumptions for a 1-year old child. A small child would have a higher exposure dose than an adult because of the child's smaller body weight; therefore conclusions based on exposure doses estimated for children would be protective for adults as well.

Health Outcome Data

Health outcome data can give a more thorough evaluation of the public health implications of a given exposure. Health outcome data can include mortality information (e.g., the number of people dying from a certain disease) or morbidity information (e.g., the number of people in an area getting a certain disease or illness). The review is most informative when (1) a completed human exposure pathway exists, (2) potential contaminant exposures are high enough to result in measurable health effects, (3) there has been sufficient time since exposure occurred for the disease to have developed, (4) enough people are affected for the health effect to be measured,

and (5) a database is available to identify rates of diseases plausibly associated with the exposure for populations of concern.

A review of health outcome data was not performed for this site. As soon as ongoing contamination of municipal wells above drinking water standards was discovered, the wells were taken out of service, so the drinking water exposure pathway is incomplete (that is, people are not currently being exposed to contaminants). The past levels of exposure were below levels associated with any measureable increases in adverse health effects.

Community Health Concerns

In producing a PHA, ATSDR attempts to respond to communities' health concerns about the site. ATSDR issued a press release in the local newspaper describing ATSDR's activities, asking the community to share any health concerns related to site exposures, and providing contact information for ATSDR staff. ATSDR did not receive any health concerns. In addition, no community health concerns were identified through our discussions with EPA, EQB, PRDOH, and PRASA. ATSDR remains willing to address questions or concerns conveyed by community members during the public comment period of this public health assessment. We will include concerns and responses in the final version of the document.

Conclusions and Next Steps

Conclusions

ATSDR reached three important conclusions in the PHA:

Conclusion 1

Today, no exposures to VOCs in drinking water from the former municipal wells at the San Germán Ground Water Contamination site are occurring.

Basis for Conclusion

The affected wells have been shut down or inactive since mid-2006. Water from these wells is not available.

Conclusion 2

Past exposures to VOCs from drinking or using water from the affected wells were below levels likely to cause harm.

Basis for Conclusion

Estimated exposures for VOCs measured in municipal water from late 1999 to 2006 were below levels associated with any adverse health effects, even if people were exposed every day to the highest concentrations measured.

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More information is needed to assess other potential exposure pathways including vapor intrusion, private wells in the area, and exposure nearer to the source of contamination.

Basis for Conclusion

The source and extent of the contamination has not been identified to date. VOC levels might be higher near source areas and in any area between the source and the affected wells, increasing the potential for exposure.

Next Steps

- EPA and/or EQB should continue efforts to identify the source, characterize the extent of the contamination, and implement remedial measures to address and prevent groundwater contamination.
- ATSDR will evaluate additional data collected by EPA and update the findings of this PHA, if necessary.

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Appendix A. Explanation of Evaluation Process

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 CVs exist, we use the lower level to be protective. Exceeding a CV does not mean that health effects will occur, just that more evaluation is needed.

CVs used in preparing this document are listed below:

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 noncancer health effects are unlikely. RMEGs are derived from EPA's reference dose (RfD).

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.

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 municipal well water from the affected wells from late 1999 to mid-2006 as the main pathway of concern at the San Germán Ground Water Contamination site.

Evaluation of Public Health Implications

The next step is to take those contaminants present at levels above the CVs and further evaluate whether those chemicals may be a health hazard given the specific exposure situations at this site. 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.

Ingestion of Groundwater

The overall exposure dose of PCE was estimated for young children – considered the most sensitive to environmental toxins in many situations. Children were assumed to weigh 10 kg (22 pounds, the average weight of a one-year-old) and drink 1 liter of well water a day [14].

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 noncancer health effect in that specific situation. If the exposure dose for a chemical is greater than the health guideline, then the exposure dose is compared to known toxicological values for that chemical and is discussed in more detail in the public health

assessment (see Discussion section). These toxicological 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 estimated exposure dose by an appropriate cancer slope factor (EPA CSFs 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 7 years as a conservative worst-case exposure duration, because PCE was not detected in any of the wells until late 1999 and all the wells were not being used by mid-2006. Therefore, the maximum increased cancer risk was multiplied by the factor (7/70) to account for a less-than lifetime exposure. In this PHA, we used the estimated child dose to perform this calculation. This dose is higher than the adult dose and would result in a higher, or more conservative, estimated cancer risk.

The actual increased risk of cancer is probably lower than the calculated number, which gives a theoretical worst-case excess cancer risk. The methods used to calculate cancer slope factors assume that high-dose animal data can be used to estimate the risk for low dose exposures in humans. The methods also assume that no safe level exists for exposure. Little experimental evidence exists to confirm or refute those two assumptions. Lastly, most methods compute the upper 95th percent confidence limit for the risk. The actual cancer risk can be lower, perhaps by several orders of magnitude [21].

Because of uncertainties involved in estimating cancer risk, ATSDR employs a weight-of-evidence approach in evaluating all relevant data [22]. Therefore, the increased risk of cancer is described in words (qualitatively) rather than giving a numerical risk estimate only. Numerical risk estimates must be considered in the context of the variables and assumptions involved in their derivation and in the broader context of biomedical opinion, host factors, and actual exposure conditions. The actual parameters of environmental exposures must be given careful consideration in evaluating the assumptions and variables relating to both toxicity and exposure.

Appendix B. Glossary of Terms

The Agency for Toxic Substances and Disease Registry (ATSDR) is a federal public health agency in Atlanta, Georgia, with 10 regional offices in the United States. ATSDR serves the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and diseases from toxic substances. ATSDR is not a regulatory agency, unlike the U.S. Environmental Protection Agency (EPA), which is the federal agency that develops and enforces laws to protect the environment and human health. This glossary defines words used by ATSDR in communications with the public. It is not a complete dictionary of environmental health terms. For additional questions or comments, call 1-800-CDC-INFO.

Acute
Occurring over a short time [compare with chronic].

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

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

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

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

Carcinogen
A substance that causes cancer.

Central nervous system
The part of the nervous system that consists of the brain and the spinal cord.

Chronic
Occurring over a long time [compare with acute].

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

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

Completed exposure pathway
[see exposure pathway].

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)
CERCLA, also known as Superfund, is the federal law that concerns the removal or cleanup of hazardous substances in the environment and at hazardous waste sites. ATSDR, which was created by CERCLA, is responsible for assessing health issues and supporting public health activities related to hazardous waste sites or other environmental releases of hazardous substances. The Superfund Amendments and Reauthorization Act (SARA) later amended this law.

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

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

Dermal
Referring to the skin. For example, dermal absorption means passing through the skin.

Dermal contact
Contact with (touching) the skin [see route of exposure].

Detection limit
The lowest concentration of a chemical that can reliably be distinguished from a zero concentration.

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

Environmental media
Soil, water, air, biota (plants and animals), or any other parts of the environment that can contain contaminants.

Epidemiologic study
A study that evaluates the association between exposure to hazardous substances and disease by testing scientific hypotheses.

Epidemiology
The study of the distribution and determinants of disease or health status in a population; the study of the occurrence and causes of health effects in humans.

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

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

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

Health outcome data
Information from private and public institutions on the health status of populations. Health outcome data can include morbidity and mortality statistics, birth statistics, tumor and disease registries, or public health surveillance data.

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

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

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

Metabolism
The conversion or breakdown of a substance from one form to another by a living organism.

Metabolic byproduct
Any product of metabolism.

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

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

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

National Priorities List for Uncontrolled Hazardous Waste Sites (National Priorities List or NPL)
EPA's list of the most serious uncontrolled or abandoned hazardous waste sites in the United States. The NPL is updated on a regular basis.

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

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

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

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

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

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

Risk
The probability that something will cause injury or harm.

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

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

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

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

Substance
A chemical.

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

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

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

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

Transport mechanism
Environmental media include water, air, soil, and biota (plants and animals). Transport mechanisms move contaminants from the source to points where human exposure can occur. The environmental media and transport mechanism is the second part of an exposure pathway.

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

Other glossaries and dictionaries:
Environmental Protection Agency (http://www.epa.gov/OCEPAterms/) National Library of Medicine (NIH) (http://www.nlm.nih.gov/medlineplus/mplusdictionary.html)