Health Consultation

Sulfolane Plume in Groundwater:
Evaluation of Community Concerns about Sulfolane in Private Water Wells

NORTH POLE, ALASKA

Prepared by the
Alaska Department of Health and Social Services
Division of Public Health, Section of Epidemiology
Environmental Public Health Program

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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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Foreword

The Environmental Public Health Program within the Alaska Division of Public Health has prepared this Health Consultation under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR is part of the U.S. Department of Health and Human Services, Public Health Service. ATSDR's mission is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related exposures to toxic substances. This Health Consultation was prepared in accordance with ATSDR methodology and guidelines.

ATSDR and its cooperative agreement partners review the available information about hazardous substances at a site, evaluate whether exposure to them might cause any harm to people, and provide the findings and recommendations to reduce harmful exposures in documents called Public Health Assessments and Health Consultations. ATSDR conducts public health assessment activities for every site on or proposed for the National Priorities List (NPL; also known as the Superfund list). Health Consultations are similar to Public Health Assessments, but they usually are shorter, address one specific question, and address only one contaminant or one exposure pathway. Another difference is that Public Health Assessments are made available for public comment, while Health Consultations usually are not. Public Health Assessments and Health Consultations are not the same thing as a medical exam or a community health study.

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SUMMARY STATEMENT

INTRODUCTION	A priority of the Environmental Public Health Program (EPHP) is to ensure that residents of North Pole, Alaska have sufficient information to safeguard their health. The Alaska Department of Environmental Conservation (DEC) asked EPHP to conduct this health consultation. The purpose of the consultation was to evaluate the public health risks of consuming and using private well water contaminated with sulfolane for household purposes. This report also addresses community concerns about potential long-term health effects—specifically cancer and birth defects—from exposure to sulfolane in drinking water.
CONCLUSIONS	EPHP reached *six* important conclusions in this health consultation.
Conclusion 1	North Pole residents who consumed water with detectable levels of sulfolane from their private wells are not likely to experience negative health effects.
Basis for Decision	The levels of sulfolane in North Pole wells are low, and below those that caused subtle health effects in test animals. However, we cannot say with absolute certainty that there would not be any health effects from long-term exposure to low levels of sulfolane in drinking water, because no studies have looked at this in animals or humans.
Next Steps	North Pole residents with detectable levels of sulfolane in their well water have been given a long-term alternative water supply. EPHP recommends continued use of an alternative water source for consumption purposes, i.e., for drinking water and making foods where the water is consumed (e.g., soup, beverages). This recommendation also applies to household pets.
Conclusion 2	Using water containing sulfolane from North Pole private wells for most household activities will not harm people's health. These household activities include bathing, washing clothes and dishes, rinsing foods, and making foods where the water is discarded, e.g., boiling eggs. Based on currently available information, using well water to shower does not pose a health risk for North Pole residents, although inhaling sulfolane in water droplets during showering needs further evaluation.
Basis for Decision	Sulfolane has low permeability (less able to go through skin), and studies have shown that sulfolane is not readily absorbed by the skin or eyes. Sulfolane also has low volatility (does not readily go from a liquid to a gas or vapor that people could breathe in while showering or bathing).

	Any trace amounts of sulfolane that might remain on foods, dishes, or clothes after washing or rinsing would be extremely small, and not be of health concern.
Next Steps	EPHP will share any new data, should it become available, regarding effects from exposure to sulfolane in well water during showering or bathing, or from other household uses.
Conclusion 3	Eating sampled parts of edible plants (fruits and vegetables) that were tested for sulfolane uptake from seven North Pole gardens is not expected to harm people's health.
Basis for Decision	Sulfolane levels detected in sampled parts of edible plants from seven local gardens during the summer of 2010 were below levels of health concern. However, the 2010 garden sampling project was very limited, and should not be generalized to all North Pole gardens or future growing seasons.
Next Steps	North Pole gardeners with detectable levels of sulfolane in their well water have been given the option of an alternative water supply for gardening purposes. EPHP recommends using an alternative water source for growing edible plants.
Conclusion 4	Sulfolane exposure from incidental ingestion of soil (i.e., accidentally eating small amounts of soil) or pica behavior (intentionally eating soil) is not expected to harm people's health.
Basis for Decision	Exposure to sulfolane from ingestion of soil that has come in contact with well water containing sulfolane was not evaluated in North Pole, due to lack of data. However, studies in the scientific literature have shown that sulfolane does not readily stick to soils.
Next Steps	Flint Hills and DEC plan to collect local soil samples to test for sulfolane. EPHP will evaluate those test results, when available, for potential health risks and notify community members of their findings.
Conclusion 5	An increase in cancer rates for North Pole residence compared to the entire state from 1996—2007 was not detected.
Basis for Decision	An analysis of data from the Alaska Cancer Registry showed that North Pole residents in census tract 16 (area that includes nearly all of the sulfolane plume) did not have a statistically significant higher overall cancer rate compared to the entire state from 1996—2007.

Next Steps	EPHP will share the findings of this health consultation with the community of North Pole and interested stakeholders.
Conclusion 6	An association between living in North Pole and an increased prevalence of birth defects from 1996—2009 was not detected.
Basis for Decision	An analysis of the data from the Alaska Birth Defects Registry did not find an association between North Pole maternal residence and an increased prevalence of birth defects from 1996—2009.
Next Steps	EPHP will share the findings of this health consultation with the community of North Pole and interested stakeholders.

I. OVERVIEW

In October 2009, the chemical sulfolane—used by the Flint Hills refinery in North Pole, Alaska to process crude oil—was detected in private drinking water wells near the refinery. In response, Flint Hills began testing all drinking water wells in the area and providing bottled water to affected residents. The Alaska Department of Environmental Conservation (DEC) contacted the Alaska Department of Health and Social Services (DHSS), Division of Public Health, to help address community concerns and evaluate potential risks to human health.

The Alaska Division of Public Health's Environmental Public Health Program strives to ensure that the people of Alaska have the information they need about contaminants in the environment to safeguard their health. We evaluated the health risks posed to North Pole residents whose wells were impacted by sulfolane. We worked with our federal partners at the Agency for Toxic Substances and Disease Registry (ATSDR) to establish a "public health action level" for sulfolane in drinking water to protect the North Pole community. Sulfolane is not a federally regulated drinking water contaminant. In addition, very little is known about the long-term effects of sulfolane on human health. After reviewing the science and conducting extensive analyses, ATSDR developed action levels for this site for three different age groups, with the lowest action level at 20 parts per billion (20 ppb) for infants.

This health consultation used ATSDR's action levels for sulfolane in drinking water and available studies, to evaluate the possible ways in which North Pole residents could be exposed to sulfolane and the potential risks to health. This included cooking and preparing food, showering and bathing, cleaning clothes and dishes, and growing food crops. We also addressed the use of well water for household pets and animals. The current use of well water for drinking was not included because affected residents have been using bottled water.

Based on the chemical properties of sulfolane and what we know from animal studies, the levels of sulfolane found in North Pole area wells pose little to no health risk when used for a number of household activities. Because few studies have tested sulfolane uptake in edible plants (i.e., fruits and vegetables), we sampled a limited number of plants from local gardens to see if eating those plants might pose a health risk. Although we did not find the levels of sulfolane in sampled edible plants to be of health concern, we recommend using an alternative water supply for gardening, until more is known about sulfolane uptake in edible plants.

Finally, in response to community concerns about whether the rates of cancer and birth defects are higher in North Pole compared to the rest of the state, Alaska Division of Public Health staff reviewed data from the state's cancer and birth defects registries. Rates for all types of cancer combined were not significantly higher in North Pole. Similarly, data from the birth defects registry did not show an association between maternal residence in North Pole and the likelihood of being reported with a birth defect. In other words, mothers who lived in North Pole at the time of delivery were not more or less likely to give birth to a child with a birth defect than mothers who lived elsewhere in the Fairbanks North Star Borough or the rest of the state.

II. BACKGROUND

Site History

Flint Hills Resources is an independent refining and chemicals company based in Wichita, Kansas. Its refineries produce fuels that power much of Texas, the Midwest, and interior Alaska. Flint Hills' refinery in North Pole, Alaska has a crude oil processing capacity of about 220,000 barrels per day. The plant processes North Slope crude oil and supplies gasoline, jet fuel, heating oil, diesel, gas oil and asphalt to Alaska markets. The refinery produced its first barrel of product in August 1977 under the ownership of Earth Resources, two months after crude oil began to flow through the Trans Alaska Pipeline. MAPCO Alaska Petroleum Inc. bought the plant in 1980 and expanded production to include gasoline and asphalt, in addition to jet fuel, heating oil, and diesel. MAPCO merged with the Williams Companies in 1998, and then sold the facility to Flint Hills Resources in 2004 (http://www.fhr.com/about/default.aspx).

In October 2009, Flint Hills detected the chemical sulfolane in new monitoring wells[1] they had installed immediately north of the refinery's property, near private homes. At the time, sulfolane concentrations (levels) in the new monitoring wells were below DEC's groundwater cleanup standard of 350 parts per billion (350 ppb). For reference, one ppb is roughly equal to one drop of water in an Olympic-size swimming pool[2].

Sulfolane was first used at the refinery in 1985 when an extraction unit was installed. Sulfolane may have been accidentally released from the new unit as early as 1986 when a large petroleum spill occurred. However, no one tested for it at that time because sulfolane was not on the federal or state's list of regulated chemicals, nor was it on the list of contaminants of concern for a typical fuel spill. The U.S. Environmental Protection Agency (EPA) has no cleanup level for sulfolane in groundwater. The chemical is also not a regulated drinking water contaminant, so there is no established "maximum contaminant level" for sulfolane in public drinking water systems or private wells.

The presence of private wells down-gradient of the refinery and the lack of federal or state standards for sulfolane in drinking water prompted testing of wells on and off the refinery's property. Once testing had confirmed that sulfolane had migrated off-site into private wells, DEC contacted DHSS to help address community concerns and evaluate potential risks to human health. In addition, Flint Hills began identifying and testing all private drinking water wells in the area, and providing bottled drinking water to affected residents and local businesses. To date, Flint Hills has tested 528 private wells and provided long-term alternative water supplies to 219 homes and commercial locations. The company has also provided bottled water to over 200 additional homes with non-detections out of an abundance of caution. Of the private wells tested, 247 had detectable levels of sulfolane (above 10 ppb). The levels ranged from non-detect to 443 ppb, with 88 between 10 and 20 ppb, 29 between 20.1 ppb and 32 ppb, 38 between 32.1 and 70 ppb, and 92 over 70 ppb.

[1] Monitoring wells are used to test and monitor groundwater quality. Their installation is regulated by DEC. These wells can be temporary or permanent, depending on their purpose.

[2] An Olympic size pool is 50 x 25 meters (164 x 82 feet) and holds about 660,000 gallons.

In March 2010, DEC's Contaminated Sites Program created a Technical Project Team to provide comprehensive and coordinated oversight for the investigation of sulfolane in North Pole's groundwater. The team consists of local, state, and federal experts in the fields of toxicology, engineering, hydrology, and environmental chemistry, to ensure that human health and the environment are protected. It has specialized subgroups that focus on specific questions having to do with sulfolane toxicology, site characterization and remediation (cleanup), chemical analysis and data quality, drinking water treatment, and community involvement and communication.

The groundwater investigation has been ongoing since 2009, and cleanup efforts continue to expand. Flint Hills has installed additional monitoring wells, as needed, to better understand and track the local groundwater flow and movement of sulfolane over time. Work on delineating (outlining) the entire area of concern, or plume, is nearly complete (Figure 1). Identifying the boundaries of the plume is done by testing for sulfolane in monitoring wells in a horizontal spread (moving outward from the source) until the chemical is not detected. Work on delineating the vertical spread of the plume (the depth of the plume) is ongoing. More information is available on DEC's North Pole Refinery Site Summary website: http://dec.alaska.gov/spar/csp/sites/north-pole-refinery.

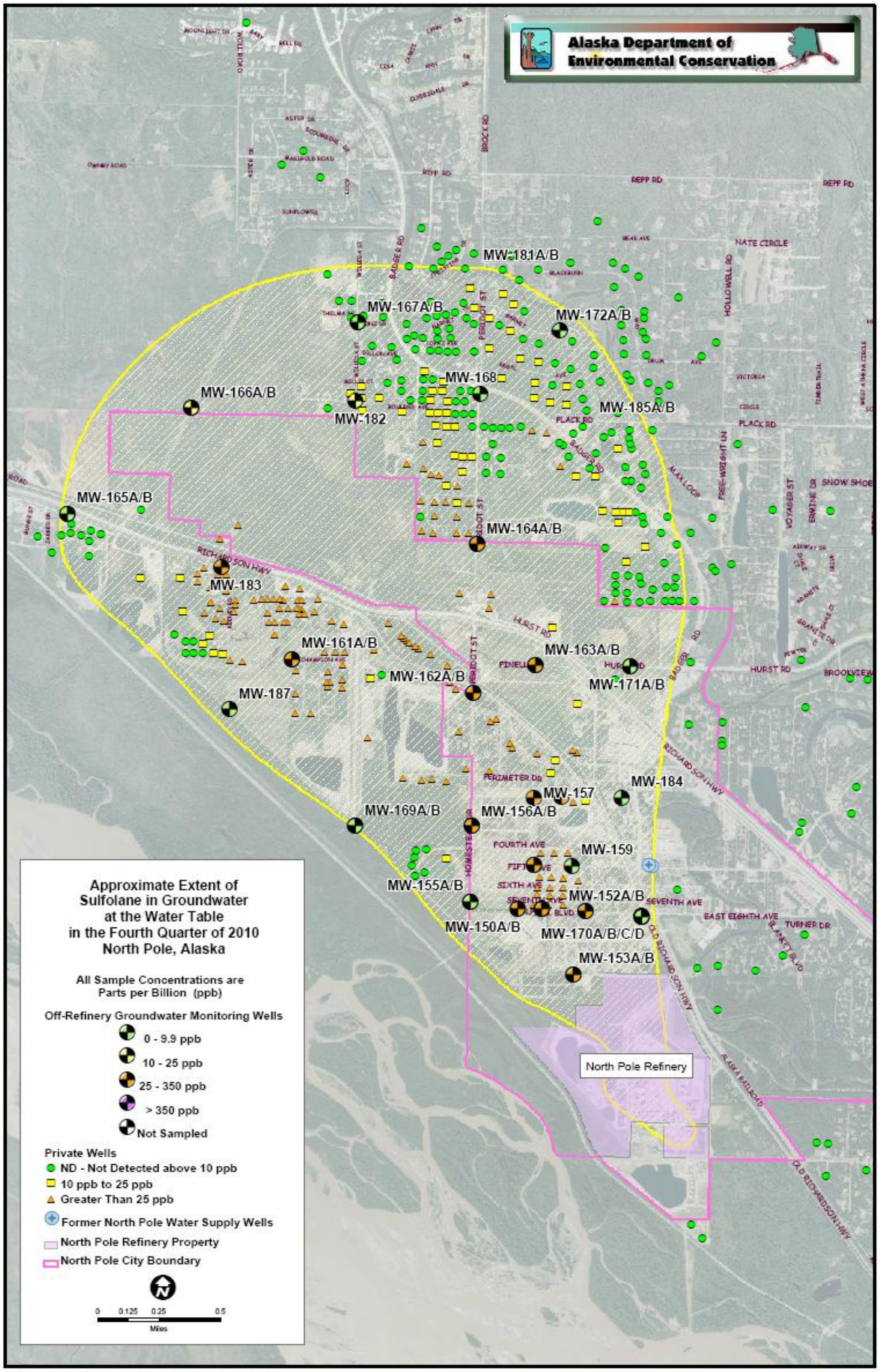
Community Description

North Pole is a small city within the Fairbanks North Star Borough in interior Alaska. It lies 13 miles southeast of Fairbanks and 385 miles north of Anchorage on the Richardson Highway, and is part of the Fairbanks metropolitan census area. The population of North Pole in 2009 was about 2,117 (U.S. Census Bureau, 2010), with a median household income of $44,583 (U.S. Census Bureau, 2000). The city covers an area of 4.2 square miles between Fort Wainwright and Eielson Air Force Base, and between the Chena River and the Tanana River, including subdivisions off of Badger Road. In 2004, the population was 81% White, 5.7% Black or African American, 3.6% Alaska Native or Native American, 2.6% Asian, 0.5% Pacific Islander, 1.2% from other races, and 5.6% from two or more races, with 3.8% Hispanic or Latino of any race (U.S. Census Bureau, retrieved 2011). North Pole's major industry aside from tourism is petroleum refining. Flint Hills Resources operates the larger of two local refineries.

Community Health Concerns about Sulfolane

In order to determine whether a contaminant in the environment might pose a health risk to people, and how much of a risk there might be, we first need to identify ways by which people can be exposed to (come in contact with) the contaminant of concern. As mentioned earlier, North Pole residents who had detectable levels of sulfolane in their wells, or who had a neighbor with a detectable level, were given bottled drinking water, so consuming their well water for drinking purposes was no longer a source of exposure. However, the community had concerns about other uses of well water, such as cooking and preparing food, showering and bathing, washing clothes and dishes, giving it to their pets, and growing food. This report examines these different ways, or "routes of exposure," by which people or their pets could be exposed to sulfolane in their well water.

Figure 1: Map of the Sulfolane Plume Area of Concern in North Pole, Alaska



Base Map: GINA-SDL, Data: Flint Hills-Shannon and Wilson, Created By DEC-WB, Date: Jan 24, 2011 (rev.4-11-11)

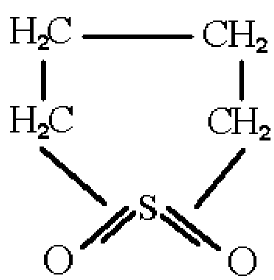
In addition, North Pole residents have expressed concerns about past exposure to sulfolane, given that some people may have been exposed to the chemical in their well water for many years. They have questions about whether their community has experienced (or will experience) any long-term health effects, such as cancer and birth defects, and whether state health officials were planning to conduct any health studies to look for potential long-term health effects. We cannot thoroughly evaluate potential health risks from past exposure to sulfolane because we do not know what the levels of sulfolane in people's wells were in the past. However, we did ask the state registries, which have collected information on cancer and birth defects since 1996, to see if the rates of these conditions appeared to be unusually high in North Pole.

III. SULFOLANE TOXICOLOGY AND HUMAN HEALTH

Basic Chemistry and Toxicology of Sulfolane

Sulfolane—or 2,3,4,5-tetrahydrothiophene 1,1-dioxide—is a man-made industrial solvent commonly used in gas production and oil refining (Brown et al., 1966; Andersen, 1976; HSDB, 2006). Sulfolane is classified as a sulfone, a group of organosulfur compounds containing a sulfonyl functional group[3]. The sulfonyl group is a sulfur atom with two double bonds to two oxygen atoms (Figure 2). The sulfur-oxygen double bond is highly polar, which makes it very soluble (readily dissolved) in water. The presence of the four-carbon ring allows for some non-polar stability. These properties make sulfolane miscible (able to mix with) in both water and hydrocarbons, which is why it is used as a solvent for purifying hydrocarbon mixtures.

Figure 2: Chemical Structure of Sulfolane



Sulfolane is also used in other manufacturing industries such as plastics, textiles, pharmaceuticals, and electronics (HSDB, 2006). It has no odor and dissolves readily in water, acetone, glycerol and many oils (Brown et al., 1966). It has low volatility (does not readily move from a liquid phase to a gas phase) and low viscosity (flows easily; Brown et al., 1966). When sulfolane gets into the environment, it tends to dissolve into water rather than attach to the soil or evaporate. As a result, sulfolane tends to move into groundwater once it gets into the environment. Once in groundwater, sulfolane spreads out and gets diluted (becomes less concentrated) as it travels with groundwater flow. Sulfolane does not break down easily in groundwater. It breaks down faster in surface water bodies where nutrients and oxygen are

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[3] In organic chemistry, functional groups are specific groups of atoms within molecules that are responsible for the characteristic chemical reactions of those molecules.

present. Some plants can take up sulfolane from water; however, it does not build up or accumulate (biomagnify) in aquatic food chains (Doucette et al., 2005).

No studies have looked for health effects in people who have been exposed to this chemical. Most of what we know about how sulfolane might affect human health comes from studies where laboratory animals were exposed to *very high* levels of sulfolane for short periods of time (up to six months). Animals exposed to very high doses of sulfolane (over 200 milligrams per kilogram body weight, or 200 mg/kg) showed acute, or short-term, effects on the central nervous system, such as hyperactivity, convulsions, hypothermia, and sometimes death at the highest doses (Andersen et al., 1977; Brown et al., 1966; Burdette and Dyer, 1986; Dyer et al., 1986).

Animal studies show that sulfolane is rapidly absorbed from the stomach into the bloodstream when it is consumed. It is also rapidly excreted (removed), with a half-life of 3.5 to 5 hours (meaning that every 3.5 to 5 hours, half of the amount remaining in your body will be gone; Zhu et al., 1988). Sulfolane is not well absorbed through human skin (Ursin et al., 1995), nor does it tend to irritate the skin or eyes of animals, even at very high concentrations. One study applied pure sulfolane to the bare skin of test animals nearly every day for over four weeks and found no skin irritation (Brown et al, 1966). This study also applied pure sulfolane into rabbits' eyes, which caused mild conjunctivitis (pink-eye) that cleared up within a few hours.

While the scientific literature has information on the acute (short-term) and sub-chronic (intermediate-term) health effects of ingesting sulfolane in a number of animal species, there are no data on the chronic, or long-term, health effects of sulfolane when exposed for a year or longer. The longest sub-chronic study was six months (Zhu et al., 1987). In these sub-chronic toxicology studies, sulfolane affected certain organs, including the liver, kidneys, and spleen, and lowered white blood cell counts in test animals.

No chronic studies in animals have been done to see if sulfolane can cause cancer or any other long-term health effects. In most laboratory tests with bacteria or animal cells, sulfolane did not cause cancer-like changes to the cells. This finding is also supported by computer modeling, which showed that sulfolane is not a carcinogen (cancer-causing agent). Computer modeling predicted that sulfolane may be mutagenic (cause gene changes), but laboratory tests showed that sulfolane is not mutagenic (ATSDR, 2010).

Animal studies suggest that sulfolane at high doses could cause specific developmental problems. When sulfolane was fed to pregnant mice, skeletal changes were found in the fetuses at the highest dose but not at the lower test doses (Zhu et al., 1987). It is important to note that at the high dose where the fetus was impacted, there were also impacts on the mother. A more detailed review of the scientific literature on sulfolane is available elsewhere (ATSDR, 2010).

Public Health Action Levels for Sulfolane in Drinking Water

Given the lack of federal guidelines for sulfolane in drinking water, DHSS asked the Agency for Toxic Substances and Disease Registry (ATSDR) to help review the toxicity (health effects) research and recommend a protective level for sulfolane in drinking water, as well as to describe potential health effects of sulfolane exposure. ATSDR is a federal public health agency of the

U.S. Department of Health and Human Services. ATSDR responds to public concerns and provides information to prevent harmful exposures and diseases from toxic substances.

In February 2010, ASTDR released its first health consultation on sulfolane, which recommended "public health action levels" for sulfolane in North Pole drinking water for infants, children, and adults (ATSDR, 2010). In May 2011, ATSDR issued a second health consultation on sulfolane with slightly lower action levels (ATSDR, 2011). A public health action level is a recommended, but not required (i.e., non-regulatory), level above which a public health intervention might be needed. Public health interventions are actions taken to reduce further chemical exposure, such as switching to another drinking water source. An action level can be used as a screening tool, because water concentrations of a chemical (contaminant) below that amount do not pose a public health concern.

As described in ATSDR's 2010 report, ATSDR's Division of Toxicology and Environmental Medicine reviewed all the toxicity studies and reports on sulfolane that were publicly available. All of these studies looked at the health effects from either acute (one to 14 days) or sub-chronic (15 to 364 days) exposure to sulfolane at high doses in test animals. Acute animal studies typically involve a single exposure to a very high, generally lethal (deadly) dose. ATSDR did not find any chronic studies (exposure for a year or longer) for sulfolane.

As mentioned earlier, the longest sub-chronic study was by Zhu et al. (1987). This study looked at guinea pigs after six months of daily oral exposure to sulfolane in food at four different doses: 0.25, 2.5, 25, and 250 milligrams of sulfolane per kilogram of bodyweight per day (mg/kg/d). This study found changes to the liver and spleen at all dose levels except the lowest dose. Based on these experiments, the study researchers identified a **No Observed Adverse Effect Level, or NOAEL, of 0.25 mg/kg/d** for guinea pigs orally exposed to sulfolane. A NOAEL is the *highest* dose (amount per unit of body weight) of a chemical that has been found to have *no* harmful health effects in animal studies.

ATSDR used the results from the Zhu guinea pig study to develop action levels for sulfolane in North Pole drinking water. As described in the first health consultation, ATSDR took the NOAEL dose of 0.25 mg/kg/d and divided it by 100 to come up with a "screening" dose for sulfolane in drinking water of **0.0025 mg/kg/d**. This dose was then multiplied by average body weight (in kilograms) and divided by average water intake (in liters) to come up with an action level for a given age group as follows: **25 ppb for infants, 40 ppb for children, and 87.5 ppb for adults** (Appendix A).

The divider of "100" used to calculate the oral dose represents two "uncertainty factors" (multiplied together) to account for areas where there is little scientific data. One uncertainty factor of 10 was used to account for potential differences in sulfolane sensitivity between test animals and humans. Another uncertainty factor of 10 was used to account for population differences in sulfolane sensitivity (meaning that some people are likely to be more sensitive to sulfolane than others).

The sub-chronic health effects found in test animals occurred at sulfolane doses that were several hundred-fold higher than what a person would be exposed to from drinking water from North

Pole wells. In the absence of human health data, scientists commonly use animal studies and computer modeling to determine what is a "safe level" of exposure to a chemical for people. When there is more uncertainty about a chemical, scientists use a higher "uncertainty factor" or layer of protection to derive a level that safeguards human health.

After the release of 2010 report, ATSDR received additional input from scientific experts outside the agency on how the action levels were derived. In response, ATSDR issued a second health consultation in May 2011, with revised action levels as follows (for development of levels see Appendix A):

- **20 ppb for infants** (assumes 1 liter water per day at 10 kilograms body weight)
- **32 ppb for children** (assumes 1 liter water per day at 16 kilograms body weight)
- **70 ppb for adults** (assumes 2 liters water per day at 70 kilograms body weight)

These slightly lower action levels reflect a slightly lower calculated oral dose for sulfolane in drinking water from 0.0025 mg/kg/d to 0.0020 mg/kg/d. The small difference between the original and revised calculated oral doses was the result of applying different Benchmark Dose modeling instead of using the NOAEL from the Zhu et al. (1987) guinea pig study, and applying a third uncertainty factor of 10 to account for potential differences in sulfolane sensitivity between sub-chronic and chronic exposure. The result was that, although different methods were used, the revised action levels are very close to the original action levels.

While sulfolane levels currently in 159 of the private wells tested were higher than the lowest ATSDR action level of 20 ppb for infants, we conclude that health effects from consuming sulfolane-impacted well water are not likely, for the following reasons:

- The ATSDR action level is a screening level, and not a clear line between safe and unsafe. It is used as a first step to identify potential contaminants of public health importance for further detailed evaluation, and is therefore set approximately 1,000 times lower than levels that caused health effects in animals.

- The health effects considered were minor and reversible, meaning that the effects were not permanent. For example, reduced white pulp in the spleen would be considered a minor adverse health effect because it does not significantly compromise spleen function and humans can live without the spleen. In addition, the liver can fully recover from fatty deposits once exposure stops.

- At current concentrations of sulfolane in drinking water, the levels of exposure remain lower than where effects in animals could occur.

- Structurally similar compounds such as sulfolene and dimethyl sulfone (a dietary supplement) do not pose a high toxicity risk. These chemicals have been studied chronically.

Thus, it is unlikely that North Pole residents who drank well water with levels of sulfolane higher than ATSDR's recommended levels would experience health effects resulting from exposure to sulfolane.

IV. USES OF WELL WATER FOR DAILY HOUSEHOLD ACTIVITIES

Cooking and Preparing Food

Affected residents who have an alternative water source, such as bottled water, for drinking and eating, should continue to use that source for making foods where the water is consumed, like soup and beverages. On the other hand, using well water to cook foods where the water is tossed out, (e.g., pasta, boiled eggs) poses no health risk at the levels of sulfolane found in North Pole wells. Any trace amount of sulfolane that might remain on foods after washing or rinsing would be too small to be of health concern.

Bathing and Showering

Based on currently available information, using well water to shower and bathe does not pose a health risk for North Pole residents. Sulfolane has low permeability (less able to go through the skin); studies have shown that sulfolane is not readily absorbed by the skin (Ursin et al., 1995). In other words, human skin is a very good barrier for keeping sulfolane from reaching the bloodstream.

In addition, sulfolane has low volatility, which means that it does not readily go from a liquid to a gas (vapor) that people could breathe in while bathing or showering (see page 8 under "Basic Chemistry and Toxicology of Sulfolane" for more information on this topic). There is no available information regarding the potential impacts associated with inhaling sulfolane in water droplets during showering. This route of exposure needs further evaluation.

Washing Dishes and Clothes

Using well water to clean dishes or clothes does not pose a health risk. Any trace residue of sulfolane that might remain after washing would be too small to be of health concern.

Drinking Water for Pets and Other Household Animals

Affected residents should continue to use their alternative water source for pets and other household animals (e.g., chickens).

Watering Plants and Grass

As mentioned earlier, sulfolane is not readily absorbed by the skin. Thus, dermal (skin) contact with plants and grass that have been watered with sulfolane-impacted well water does not pose a health risk.

The physical properties of sulfolane suggest that it does not stick to soil very well; however, we do not know that for certain. Studies are underway to determine whether sulfolane sticks to soil, and if so, how much. If sulfolane does remain in soil from above-ground watering, it could be a concern for those who ingest soil incidentally from hand-to-mouth exposure (e.g., handling soil and then not washing hands before eating) or through pica. Pica is the repeated ingestion, or swallowing, of unusually high amounts of soil (on the order of one to five grams, or up to about a teaspoon a day). Groups at risk for pica behavior include children age six and younger, and people who are developmentally delayed. A small percentage of pregnant women also exhibit pica for unknown reasons (Horner et al., 1991). The Technical Project Team plans to test soil for sulfolane in the near future to see whether sulfolane remains in soil once it is in the environment.

Growing Foods

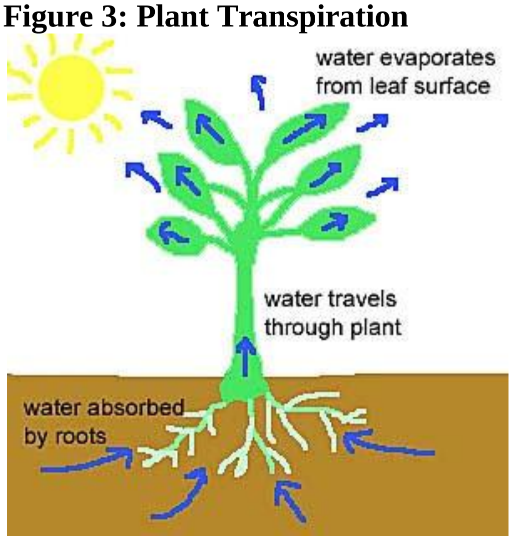
North Pole residents wanted to know whether it was safe to eat fruits and vegetables that were grown with well water containing sulfolane. A few studies have found that some plants can take up sulfolane along with the water, but none of the studies had tested edible plants (ones that people eat) grown in "real world" situations. In response, the Technical Project Team conducted a garden sampling project during the summer of 2010, to see whether edible plants in people's gardens could take up sulfolane from well water, and if so, whether the levels of sulfolane in those plants could pose a health risk to the people who eat them. The following section describes this project in more detail.

V. GARDEN SAMPLING PROJECT

Background

Studies show that plants can absorb (take up) sulfolane from water; how much depends on a number of factors, such as: 1) the type of plant (e.g., cattail, shrub); 2) the part of the plant (e.g., leaf, stem, fruit, flower, root); and 3) the plant's growing conditions. Studies have found a wide range of sulfolane levels in different parts of the same plant, for example roots versus leaves. Sulfolane is taken up with the water by the roots and moved to other parts of the plant, like the leaves and flowers (Headley et al., 1999; Dettenmaier et al., 2009). This is because water moves from the ground into the plant and evaporates out through the leaves in the transpiration process (Figure 3). As a result, sulfolane does not tend to concentrate within the roots, but instead tends to build up in the parts of the plant that grow above the ground where transpiration occurs.

Figure 3: Plant Transpiration



Based on these findings, we suspected that if edible plants from people's gardens could take up sulfolane, it would most likely be found in the leaves and not the roots. So, root vegetables, like carrots and potatoes, and other "below-the-ground" vegetables, would be less of a health concern than leafy vegetables and those with high water content, like lettuce and tomatoes. In addition, whether or not the amount of sulfolane in edible plants would be high enough to pose a health risk would depend on many factors, such as the level of sulfolane in the well water, how much well water was used, and what parts of the plant and how much and how often they were eaten.

Sampling Methods

A total of seven North Pole gardeners participated in this project. Plant samples were collected three times during the growing season. The first sampling event occurred in July at early harvest, the second in August, and the third in September at late harvest. We sampled a variety of plants, including lettuce, rhubarb, cucumber, peas, zucchini, tomatoes, currants, carrots, beets, and broccoli. Samples included the edible (i.e., most commonly eaten) parts of plants, like the lettuce leaf, rhubarb stem, zucchini fruit, and carrot root. We also tested the non-edible rhubarb leaf. Samples of the well water used for gardening were also collected at the same time as the plant samples. All plant samples were sent to an outside laboratory for analysis, while the water samples were analyzed by two in-state laboratories. Sampling and analysis methods were reviewed and validated by the Technical Project Team's chemistry subgroup, which includes the Alaska State Public Health Laboratory.

Results of the Plant and Water Sampling

A total of 56 samples from 27 different types of plants were collected during July–September 2010. Different parts of plants (e.g., roots, stems, leaves, fruits and flowers) were tested for sulfolane content. Table 1 lists the types and parts of plants that were sampled, along with the range of sulfolane concentrations (in ppb) found in the plants. The table also shows how many samples of each type of plant were tested and how many samples had detectable levels of sulfolane.

The levels of sulfolane range from non-detect (below a level that the laboratory could measure) to 198 ppb in a beet leaf. Fewer than half (21 out of 56) of the samples had detectable levels of sulfolane. Of those, about half (n=11) were the leafy part of the plant.

Some samples are noted in the table as having an EMPC flag. The EMPC flag, or "*estimated maximum possible concentration*," means that the laboratory could not say for certain whether sulfolane was present; however, if there, the *maximum* possible concentration that could be present in the sample is provided. For example, one carrot sample tested at 8.4 ppb sulfolane with an EMPC flag. This means that the laboratory could not be certain that what was in the carrot sample is actually sulfolane, but if so, the level of sulfolane would be no greater than 8.4 ppb. Given this uncertainty, all five samples with an EMPC flag were treated as though they contained sulfolane at the level provided by the laboratory. This approach is conservative (i.e., we treated it as a "worst case scenario") because the actual amount of sulfolane in the plant sample was either zero or up to the level reported by the laboratory.

Table 1: Concentrations of Sulfolane in Sampled Plants

Sample Type	Range of Results (ppb)	Number of Samples	Number of Detections	Notes
Beet root	ND – 15.2	3	1	
Beet leaf	28.4 – 198	2	2	
Broccoli	18.6	1	1	
Cabbage	11	1	1	
Carrot	ND – 8.4	4	1	EMPC
Cauliflower	ND – 15.9	2	1	EMPC
Crab apple	ND	1	0	
Cucumber	ND	2	0	
Currant	41.1	1	1	EMPC
Green leaf lettuce	25 – 92.8	3	3	
Green onion	ND	1	0	
Potato	8.9	1	1	EMPC
Radish root	ND	1	0	
Red leaf lettuce	41.4 – 64.8	2	2	
Rhubarb leaf*	ND – 118	5	3	
Rhubarb stem	ND	5	0	
Romaine lettuce	ND	1	0	
Shucking peas	ND	2	0	
Snap peas	ND – 12.5	3	1	
String beans	ND	1	0	
Summer squash	ND	1	0	
Swiss chard leaf	ND	1	0	
Swiss chard stem	ND	1	0	
Tomato	ND – 28.1	4	2	
White onion	ND	2	0	
Zucchini blossom (flower)	ND	1	0	
Zucchini fruit	ND – 24.7	4	1	EMPC

EMPC = estimated maximum possible concentration for detected sample
ND = not detected
*Note: rhubarb leaves are poisonous, and should not be eaten

Table 1 shows that sulfolane was detected in the following parts of plants:

- Leaves (beet leaf, cabbage, green leaf lettuce, red leaf lettuce, and rhubarb leaf);
- Fruit (currant, snap pea, tomato, and zucchini);
- Flowers and stems (broccoli and cauliflower); and
- Roots (beet root, carrot, potato).

The following edible parts of plants showed no detectable levels of sulfolane: crab apple, cucumber, green onion, radish root, rhubarb stem, romaine lettuce, shucking peas, string beans, summer squash, swiss chard (leaf and stem), white onion, and zucchini blossom (flower).

As noted earlier, samples of the well water used for gardening were collected at the same time as the garden plants. A total of 16 well water samples were collected from the seven locations. The sulfolane levels ranged from 31.5 to 247 ppb. Not enough samples were collected to see if there was a relationship between sulfolane levels in well water and sulfolane levels in plants from the same garden.

Calculating Screening Values for Sulfolane in Edible Plants

In order to determine whether eating any of the sampled plants that contained sulfolane could be harmful, we compared the levels of sulfolane in each plant to a "screening value" we calculated for eating fruits and vegetables. This screening value is based on the same oral dose of 0.002 mg/kg/d that ATSDR used to develop their action levels for sulfolane in drinking water, but it includes different assumptions about exposure, to account for food intake rather than water intake.

Similar to the action levels for sulfolane in drinking water, we calculated different screening values for eating fruits and vegetables that contain sulfolane, by age group (Appendix B). For adults, the screening value we calculated for sulfolane intake from these foods is **215 ppb**. In other words, a level of sulfolane *at or below* 215 ppb in these foods is not likely to pose a health risk for adults. For children three to six years old, the screening value is **73 ppb**; for toddlers one to three years old, the screening value is **56 ppb**; and for infants (up to one year old), the screening value is **48 ppb**. The reason these screening values are higher than the ATSDR action levels for drinking water (e.g., 48 ppb versus 20 ppb for infants) is because we consume much more water than we do fruits and vegetables. These screening values are also based on very conservative (meaning very protective) risk assessment calculations that assume the following:

- *All* of the fruits and vegetables a person eats has levels of sulfolane like those in the plant sampled;
- A person eats a lot more fruits and vegetables than the average person in that age group (i.e., in the 95th percentile); and
- A person eats them almost every day (350 days per year), year after year.

Further Evaluation of Edible Plants that Exceeded Screening Values

If the amount of sulfolane found in a plant exceeded (was above) an age-specific screening value (e.g., 48 ppb for infants), we further analyzed the data to assess potential health risks. This was done because our calculated screening values assume that a person eats only one type of food item—for example, carrots—for his/her *entire* intake of fruits and vegetables. Because most people eat a variety of foods, we looked more closely at any sampled plant that had a sulfolane level above a screening value; this included beet leaf, green lettuce, and red lettuce (Table 2). We used the highest sulfolane concentration detected in each of these plants (198 ppb for beet leaf, 92.8 ppb for green lettuce, and 64.8 ppb for red lettuce, Table 1) and the mean, or average, intake rate for that plant, to calculate the dose of sulfolane a person would be exposed to from eating that food.

The likelihood of harmful effects from a contaminant in food depends on how much is in the food, how much of that food a person eats, and how often he/she eats it. These factors are important for calculating a dose (see Appendix B). In this evaluation, the dose is a measure of exposure to sulfolane relative to: 1) body weight; 2) duration of the exposure (how long a person was exposed); and quantity of that food consumed (how much of the food a person eats). The intake rates (how much and how often a food is eaten) we used to calculate the exposure dose were the mean values obtained from national food surveys and reported in the EPA Exposure Factors Handbook by age group (EPA, 2011). In making these calculations, we can more accurately evaluate the amount of sulfolane that each age group would actually be exposed to from eating that food.

Next, we compared these calculated doses to ATSDR's site-specific oral dose (0.0020 mg/kg/d) to see whether eating foods with this level of sulfolane could be harmful. To be conservative, we assumed that, for example, all green lettuce eaten by an infant, toddler, or child, comes from the home garden where plants were grown with sulfolane-impacted water.

No information was available on specific intake rates for red or green lettuce, or for beet leaves, so we used the intake rates for "all lettuce types combined" and beet "fruit" (which is the root) for beet leaf.

Table 2: Calculated Exposure Dose (mg/kg-d)

Vegetable (concentration)	Infant	Toddler	Child	Adult	ATSDR Oral Dose
Beet Leaf (198 ppb)	0.000002	0.000000	0.000184	0.000057	0.0020
Green Lettuce (92.8 ppb)	0.000030	0.000062	0.000069	0.000038	0.0020
Red Lettuce (64.8 ppb)	0.000021	0.000043	0.000048	0.000027	0.0020

ppb= parts per billion
mg/kg-day= milligrams per kilogram per day
Reference: United States Environmental Protection Agency. 2011. Exposure Factors Handbook. EPA 600/R-09/052F. Intake rates taken from Table 9-6.

As shown in Table 2, none of the calculated exposure doses exceeded the ATSDR oral dose for sulfolane. So, although the highest levels of sulfolane detected in some of the red lettuce, green lettuce, and beet leaf samples were above the screening levels for some age groups, closer evaluation showed that eating them does not likely pose a health risk for any age group, in the amounts typically eaten.

The limited nature of this sampling project and environmental conditions that we could not control did not allow us to see if there was a relationship between the amount of sulfolane in well water and the amount of sulfolane that ended up in plants. However, this was not a goal of the project. We were mainly interested in finding out if sulfolane was taken up by edible plants from North Pole gardens, and if so, were the levels detected of potential health concern.

What the Levels of Sulfolane in Edible Plants Mean for Human Health

None of the sampled fruits and vegetables from the seven North Pole gardens had a sulfolane level of health concern for any age group, so eating them does not likely pose a health risk. However, this project was mainly done to provide direct feedback to participating gardeners only, and not all gardeners in North Pole. We cannot draw broad conclusions about the safe use of sulfolane-impacted well water for growing fruits and vegetables for several reasons. The testing of edible plants from people's gardens involved a very limited number of samples, and therefore should be interpreted with caution. With only seven gardens, few samples of each plant, results from only one growing season, and other factors (e.g., amount of rainfall and level of sulfolane in the water) that could affect the final levels of sulfolane in the plants, we cannot draw broad conclusions about the safe use of sulfolane-impacted water for growing fruits and vegetables for all North Pole gardeners. Therefore, we recommend using water with no detectable level of sulfolane for growing those foods, until more is known.

Nonetheless, the sampling results provide valuable information for North Pole residents. Specifically, the results from this garden sampling project show that:

- Edible garden plants can take up sulfolane that is present in water. People can be exposed to sulfolane by eating those foods.
- Sulfolane was found at low levels in all parts of plants that were sampled (leaves, fruits, flowers, stems and roots). The highest levels were found in the leafy part of the plant.
- Based upon what we know about sulfolane, the levels of sulfolane found in edible plants from the North Pole gardens we tested were low and not likely to harm health.

VI. COMMUNITY CONCERNS ABOUT LONG-TERM EXPOSURE TO SULFOLANE

North Pole residents have been concerned about potential health effects from long-term exposure to sulfolane in drinking water, and wanted to know whether we would conduct health studies to address this concern. DHSS follows ATSDR's guidance on health studies (http://www.atsdr.cdc.gov/DHS/index.html). This guidance describes the different types of health studies, as well as the requirements for conducting a successful health study. Type-1 health studies explore or generate hypotheses (scientific questions). Type-2 health studies test hypotheses about the association between health outcomes (e.g., diseases) and exposures (e.g., contaminants).

Type-1 Health Study

We conducted two Type-1 health studies which compared the rates of cancer and birth defects for North Pole to rates for all of Alaska. This was done by analyzing data from DHSS's Alaska Cancer Registry and Alaska Birth Defects Registry.

Cancer Analysis[4]

No published study has looked to see if sulfolane causes cancer in people or animals. Computer modeling suggests that sulfolane is probably not carcinogenic (i.e., does not cause cancer; ATSDR, 2010).

The Alaska Cancer Registry (ACR) is part of the Chronic Disease Prevention and Health Promotion section within the Alaska Division of Public Health. The ACR database contains information about cancer cases diagnosed in Alaska since 1996. It collects information to track cancer incidence (cases), mortality, treatment and survival.

Methods

The sulfolane plume is almost entirely contained within the Fairbanks North Star Borough Census Tract 16, and is over half the size of this census tract (see Appendix C). Because of this, Census Tract 16 was used as the basis for this analysis.

The incidence, or number of all cancer cases that occurred in a specified number of persons for a defined period of time, of all cancer sites (e.g., lung, bladder, skin) combined for the entire state of Alaska was determined based on data in the ACR database. Using the population of Census Tract 16, we calculated the number of cancer cases that would be expected for this area and compared it to the number of cancer cases that were actually observed for this area.

To see whether cancer incidence in a community is occurring at a higher or lower rate than expected, we calculated a statistic called the standard incidence ratio (SIR). The SIR is the number of observed cancer cases in a community divided by the number of expected cases, based on the population of the community and the state's cancer rates. This number is then multiplied by 100. An SIR greater than 100 means that more cancer cases occurred than expected, while an SIR less than 100 means that fewer cancer cases occurred than expected. For example, an SIR of 150 means 50% more cases occurred than expected; a SIR of 90 means 10% fewer cases occurred than expected.

To determine whether the observed number of cancer cases is significantly different from the expected number, or if the difference may be due to chance, we calculate a 95% confidence interval (CI) for the SIR. A 95% CI assesses the size and reliability of an SIR. A 95% CI is the range of estimated SIR values having a 95% probability of including the true or *actual* SIR for the population. If the 95% CI range does not include the value 100, then the study population is significantly different from the comparison or "normal" population. "Significantly different" means there is less than a 5% chance that the observed difference is the result of random fluctuation in the number of observed cancer cases. If the CI range includes 100, then the true SIR may be 100, and it cannot be concluded with enough certainty that the observed number of cases is not due to chance and reflects a real cancer increase or decrease.

Results

The results of these calculations are summarized in the following table and compared to the number of observed cases.

[4] Cancer analysis conducted by David O'Brien, PhD, Alaska Cancer Prevention and Control Program, Alaska Cancer Registry, Alaska Division of Public Health.

Cancer Type	Number of Observed Cancer Cases, 1996-2007	Number of Expected Cancer Cases, 1996-2007
All Cancer Sites Combined	127	117

As the table above shows, the number of observed cancer cases for Census Tract 16 exceeds the number of expected cancer cases for Census Tract 16 between1996 and 2007. However, to see if this excess, or difference, is not just due to chance, we applied the SIR statistical significance test described above. We calculated the SIR and the upper and lower 95% CIs (for calculations see Appendix C). The results are summarized in the following table:

Standard Incidence Ratio (SIR)	Lower Confidence Interval	Upper Confidence Interval
108.4	89.6	127.3

The SIR suggests that there are 8.4% more cancer cases in the census tract than expected. However, because the lower and upper CIs (89.6 – 127.3) include the value 100, the SIR of 108.4 is not statistically significant. Therefore, we cannot conclude with enough confidence that the observed number of cases is not due to chance and reflects a real cancer increase.

Conclusion

Based on Alaska incidence rates for all cancers combined and the population of Census Tract 16, we compared the number of expected cancer cases to the number of observed cancer cases from 1996—2007. While the number of observed cases (127) exceeds the number of expected cases (117) for that time period, the SIR statistical test shows that the difference is not statistically significant. Therefore, we cannot conclude that the observed number of cases reflects an actual increase in the number of cancer cases in this area.

Birth Defects Analysis[5]

The Maternal and Child Health Epidemiology unit within the Alaska Division of Public Health established the Alaska Birth Defects Registry (ABDR) in 1996, to provide reliable and timely information on the number of infants and young children with birth defects. An epidemiologist with the registry used ABDR data to examine the prevalence of birth defects in North Pole compared to the Fairbanks North Star Borough (FNSB) only and to the entire state. Birth defects prevalence (the number of children reported with birth defects for every 10,000 live births during the period under study) estimates how common a condition is within a defined population.

Methods

For the analysis, we combined the data for children born in 1996 through 2009 to calculate the prevalence of major congenital anomalies[6] among infants born during this period. Using

[5] Birth defects analysis conducted by Janine Schoellhorn, MS, MPH, Senior Epidemiologist, Maternal and Child Health Epidemiology Unit, Section of Women's, Children's, and Family Health, Alaska Division of Public Health.

[6] Major congenital anomalies include 45 birth defects selected for coverage by the National Birth Defects Prevention Network.

statistical techniques (multiple logistic regression), we controlled for known risk factors of birth defects that may differ between populations, such as the mother's age.

We looked at the association between the odds, or likelihood, of an infant being reported with a birth defect whose mother lived in North Pole at the time of the infant's birth (called maternal residence) and the odds of a child being reported with a birth defect whose mother did not reside in North Pole. The measure of association used in this analysis was the odds ratio (OR). An odds ratio equal to one (OR = 1) means that the health outcome is equally likely to occur in both of the groups being compared. An OR less than 1 (e.g., OR = 0.5) means that the event is less likely to occur in one of the two populations, while an OR greater than 1 (e.g., OR = 2) means that the event is more likely to occur in one of the two populations. The statistical likelihood that a calculated OR or adjusted odds ratio (aOR) is accurate depends, in part, on the confidence interval (CI) for the OR. If the 95% CI includes the value of one (e.g., CI = 0.8 – 1.9), that means we are 95% confident that the health outcome is equally likely to occur in both groups. In other words, there is only a 5% chance that there was a difference in the odds that we could not detect.

Results

A potential association between birth defects prevalence and North Pole maternal residence was investigated and compared to the birth defects prevalence in the FNSB only and the entire state. The aOR and CIs for these comparisons are provided in Table 3. Two groups—chromosomal anomalies and cardiovascular anomalies—had statistically significant ORs (their respective confidence intervals did not include the value 1), so we further investigated these two groups.

Table 3: Adjusted odds ratios (aOR) of having been reported with a major birth defect for maternal residence in North Pole, by population group, birth years 1996-2009, Alaska Birth Defects Registry, 2011.

Type of Birth Defect	Birth Population			
	Alaska		Fairbanks North Star Borough	
	aOR	95% CI	aOR	95% CI
Musculo-skeletal	1.2	0.8-1.9	1.1	0.7-1.8
Genito-urinary	1.1	0.7-1.5	1.4	1.0-2.1
Alimentary	1.2	0.9-1.7	1.5	1.0-2.2
Cardiovascular	1.3	1.1-1.6*	1.2	1.0-1.5
Central nervous system	1.3	0.8-2.0	1.2	0.7-2.1
Chromosomal	1.7	0.9-3.1	3.4	1.5-7.5*

* statistically significant at p=.05

Note: there were too few cases of eye and ear anomalies to include in the analysis.

In the analysis, we found an association between chromosomal anomalies and North Pole maternal residence in the FNSB comparison, but not in the Alaska (entire state) comparison. The only known risk factor for chromosomal anomalies, which are very rare, is maternal age. After making statistical adjustments to the data so that the maternal age distribution in all comparison communities was similar to that of Alaska overall, we compared the age-adjusted rates of chromosomal anomalies for Alaska, FNSB, North Pole and three other Alaskan communities where the number of births was similar to North Pole. The small number of cases resulted in very unstable rates (e.g., included large confidence intervals), particularly in small populations such as North Pole. The confidence intervals around the age-adjusted rates for North Pole and FNSB demonstrated that the differences in rates were not statistically significant.

Maternal residence in North Pole was marginally associated with cardiovascular anomalies in the state, but not the FNSB. On further examination of the data, it was confirmed that cardiovascular anomalies are reported more frequently in the FNSB compared to the rest of the state. The association could not be attributed to North Pole residence, but to another factor or factors that influence the rate of cardiovascular birth defects reporting in the entire borough.

Conclusion

An association between birth defects prevalence and North Pole maternal residence was not observed in either comparison population (FNSB only and the state as a whole) for any of the birth defect types. Two types of birth defects, cardiovascular anomalies and chromosomal anomalies, had odds ratios with confidence intervals that were statistically significant. These findings were investigated further and reliable explanations for the noted associations were identified (i.e., an unequal maternal age distribution among the comparison populations).

In summary, we did not find an association between North Pole maternal residence and an increased prevalence of birth defects from 1996—2009. There are many limitations that must be considered when interpreting these findings. Most types of birth defects are uncommon, as reflected by the low number of birth defects reported in North Pole during a 14-year period. It is often difficult to evaluate differences in the rates of birth defects and other rare health outcomes in small populations.

Limitations for Conducting Health Studies

A common problem in trying to compare uncommon or rare health outcomes or disease rates between communities in Alaska is small population sizes. The number of North Pole residents with sulfolane in their well water is relatively small (fewer than 250 wells), as is the population of North Pole, for conducting health studies.

Furthermore, there are other limitations that we could not control for that could affect the results of these analyses, such as how long someone had lived at a given address, and identifying those with cancer or birth defects who had moved in or out of the area.

Type-2 Health Study

Type-2 health studies are specifically designed to test scientific hypotheses about the association between adverse health outcomes and hazardous substance exposures in populations. A Type-2 health study is recommended when sufficient information and other attributes exist such that a successful study can likely be performed. These attributes include, but are not limited to: 1) the ability to document or validate human health outcomes; 2) the ability to adequately control for confounding factors and minimize biases; and 3) the ability to provide adequate study size and statistical power. Based on results from the cancer and birth defects analyses and aforementioned limitations described in this health consultation, we do not recommend a Type-2 health study regarding sulfolane exposures in North Pole at this time.

The reasons for this recommendation are multifold, and include the following: first, we know very little about the health effects of sulfolane exposure in people, making target health endpoints difficult to predict. While Zhu, et al. (1987) found changes in the liver (fatty deposits) and white blood cell counts in guinea pigs that were exposed to sulfolane, the changes were subtle and only occurred at high exposure doses of sulfolane. Furthermore, the subtle changes that were observed were "non-specific," meaning that they are commonly associated with a number of diseases and other factors (e.g., other contaminants, diet, alcohol use, smoking, genetics). Thus, there would be important confounders that we would be unable to control for. Next, as shown above, the sulfolane levels that North Pole residents were exposed to from their well water were very low compared to those used in animal studies, making the likelihood of finding these subtle/non-specific changes or any other adverse health outcomes unlikely. Finally, as noted in the limitations above, our recommendation against a Type-2 study is further supported by the fact that the exposed population in North Pole is small, which further limits the ability to provide adequate power to detect statistically significant differences in comparison groups.

VII. CHILDREN'S HEALTH CONSIDERATIONS

Infants and children are often more vulnerable to exposures than adults in communities faced with contamination of their air, water, soil, or food. This vulnerability, or sensitivity, is a result of the following factors:

- Children are smaller, resulting in higher doses of chemical exposure per body weight.
- The developing body systems of children can sustain permanent damage if toxic exposures occur during critical growth stages.

Because children depend on adults for access to housing and medical care and for identifying risks, adults need as much information as possible to make informed decisions regarding their children's health. We are committed to evaluating the special interests of children in instances where their behaviors or sensitivity to contaminants could put them at greater risk. The screening values and guidelines used in this evaluation are protective of the health of the most sensitive populations, including infants and children.

VIII. CONCLUSIONS

- Based on currently available information, North Pole residents who consumed water with detectable levels of sulfolane from their private wells are not likely to experience negative health effects. This is because the levels of sulfolane in people's wells are low, and substantially below those that caused subtle health effects in test animals. However, we cannot say with *absolute certainty* that there will not be any health effects from long-term exposure to low levels of sulfolane in drinking water because no studies have looked at this in animals or people.

- Using water containing sulfolane from North Pole private wells for most household activities will not harm people's health. These household activities include bathing, washing clothes and dishes, rinsing foods, and making foods where the water is discarded, e.g., boiling eggs. Based on currently available information, using well water to shower does not pose a health risk for North Pole residents, although inhaling sulfolane in water droplets during showering needs further evaluation.

- Eating sampled parts of edible plants (fruits and vegetables) that were tested for sulfolane uptake from seven North Pole gardens is not expected to harm people's health. Affected North Pole gardeners have been given the option of an alternative water supply for gardening purposes; therefore, we recommend using an alternative water source for growing edible plants. The 2010 garden sampling project was very limited, and should not be generalized to all North Pole gardens or future growing seasons.

- Sulfolane exposure from incidental ingestion of soil (i.e., accidentally eating small amounts of soil) or pica behavior (intentional eating of soil) is not expected to harm people's health. Exposure to sulfolane from ingestion of soil that has come in contact with well water containing sulfolane was not evaluated in North Pole, due to lack of data. However, studies in the scientific literature have shown that sulfolane does not readily stick to soils.

- An increase in cancer rates for North Pole residence compared to the entire state from 1996—2007 (when records were available) was not detected.

- An association between living in North Pole and an increased prevalence of birth defects from 1996—2009 (when records were available) was not detected.

- For the reasons described earlier, conducting a Type-2 health study to find a link between sulfolane exposure and any adverse health effects would be unlikely to yield valid scientific findings; therefore, a Type-2 health study is not recommended at this time.

IX. RECOMMENDATIONS

- North Pole residents with detectable levels of sulfolane in their well water should continue to use an alternative source of water for drinking and eating. This also applies to pets and other household animals.

- Flint Hills should continue to ensure that North Pole residents with detectable levels of sulfolane in their well water have a long-term alternative water source for drinking and cooking purposes.

- North Pole gardeners should use a water source that has no detectable level of sulfolane for growing edible plants, until more is known on the uptake of sulfolane into fruits and vegetables.

- Flint Hills and DEC should share the results of soil sampling with DHSS to determine whether contact with residential soils that were exposed to sulfolane poses a potential health risk.

X. PUBLIC HEALTH ACTION PLAN

- EPHP will distribute this report to the community of North Pole and interested stakeholders within one month of the public release of this document.

- This health consultation will be available on the DEC and DHSS websites.

- EPHP is available to assist with evaluating new scientific information regarding sulfolane that could impact public health.

- EPHP is available to assist with ongoing health education needs for the North Pole community pertaining to sulfolane exposure, as resources allow.

- North Pole residents and interested stakeholders are welcome to contact EPHP with further questions about the content of this report.

XI. ADDITIONAL INFORMATION

Previous fact sheets and other resources are available online, or you can request a copy by contacting DHSS's Environmental Public Health Program at (907) 269-8000:

- Alaska Department of Environmental Conservation North Pole Refinery Site Summary: http://dec.alaska.gov/spar/csp/sites/north-pole-refinery

- DHSS Final Results of the North Pole Garden Sampling Project (January 18, 2011): http://www.epi.hss.state.ak.us/eh/sulfolane/DHSSGardenSamplingFinalResultsFactSheet.pdf

- DHSS Results of the North Pole Garden Sampling Project: Testing of Early Harvest Plants for Sulfolane (Aug. 16, 2010): http://www.epi.hss.state.ak.us/eh/sulfolane/DHSSGardenSamplingEarlyResultsFactSheet.pdf
- DHSS Community Health Concerns about Sulfolane (April 22, 2010): http://www.epi.hss.state.ak.us/eh/sulfolane/CommunityHealthConcernsSulfolane.pdf

- DHSS Companion Guide to the ATSDR Health Consultation on Sulfolane (Feb. 9, 2010): http://www.epi.hss.state.ak.us/eh/sulfolane/DHSSSulfolaneHCCompanion.pdf

- DHSS Sulfolane Health Fact Sheet (Jan. 12, 2010): http://www.epi.alaska.gov/eh/sulfolane/SulfolaneHealthFactSheet.pdf

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Report Preparation

This health consultation for the North Pole refinery sulfolane site was prepared by the Alaska Division of Public Health under a cooperative agreement with the federal Agency for Toxic Substances and Disease Registry (ATSDR). It was completed in accordance with the approved agency methods, policies, and procedures existing at the date of publication. Editorial review was completed by the cooperative agreement partner.

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Appendix A: Calculations for Drinking Water Action Levels

ATSDR's recommended action levels for sulfolane in drinking water

Population	Sulfolane in drinking water (µg/l or ppb) – 2010 Action Levels	Sulfolane in drinking water (µg/l or ppb) – 2011 Action Levels	Water intake per day	Body weight
Infants	**25**	**20**	1 liter	10 kg (22 lb)
Children	**40**	**32**	1 liter	16 kg (35 lb)
Adults	**87.5**	**70**	2 liters	70 kg (154 lb)

Based on the 2011 ATSDR Health Consultation, the acceptable level of sulfolane in drinking water for adults is 70 micrograms of sulfolane per liter of water (70 µg/l), which is the same as 70 parts per billion (ppb). The level of 70 ppb assumes that the average adult consumes two liters (about two quarts) of water daily and weighs 70 kilograms (kg), or about 154 pounds. In the same way, the levels of 20 ppb for infants and 32 ppb for children reflect consumption of an average of one liter of water per day and bodyweights of 22 pounds and 35 pounds, respectively.

Action level in micrograms/liter = provisional health guidance value in micrograms/kilogram/day x Body Weight in kilograms/water intake in liters

For example, for an infant the dose would be:
20 micrograms/liter= 2.0 µg/kg/d x 10kg / 1 liter

Appendix B: Calculations for Plant Screening Values and Exposure Doses

TABLE 1: CALCULATION OF TARGET PLANT CONCENTRATION OF SULFOLANE

A. Intake Equation:

$$CP = \frac{THQ \times RfD \times BW \times AT}{IR \times EF \times ED}$$

B: Variables and Assumptions:

Variables	Exposure Case				Units	Citation	Description
	Infant (0-1 year)	Infant (1-3 years)	Child (3-6 years)	Adult			
CP	0.048	0.056	0.073	0.215	mg/kg	–	Screening concentration of sulfolane in plants (as consumed)
THQ	1.0				unitless	18 AAC 75	Target hazard quotient
RfD	0.0020				mg/kg-d	ATSDR	oral reference dose
BW	9.2	11.4	18.6	70	kg	EPA 2011	body weight
AT	ED x 365				days	EPA 1989	Averaging time - noncarcinogens
IR	0.40388	0.4218	0.5301	0.679	kg/day	EPA 2011	95th percentile consumers only vegetable + fruit ingestion (body weight adjusted) Tables 9-1 from EPA 2011
EF	350	350	350	350	day/year	EPA 1991	residential exposure frequency
ED	1	2	3	30	year	EPA 1991	residential exposure duration

TABLE 2: CALCULATION OF EXPOSURE DOSE FOR SULFOLANE IN PLANTS

A. **Dose Equation:**

$$Dose = \frac{CP \times IR \times EF \times ED}{BW \times AT}$$

B: Variables and Assumptions:

Variables	Exposure Case				Units	Citation	Description
	Infant (0-1 year)	Infant (1-3 years)	Child (3-6 years)	Adult			
Dose	See Table 3				mg/kg-d	–	Calculated Exposure Dose
CP (Beet Leaf)	0.198				mg/kg	–	Actual Plant Concentration
CP (Green Lettuce)	0.0928				mg/kg	–	Actual Plant Concentration
CP (Red Lettuce)	0.0648				mg/kg	–	Actual Plant Concentration
BW	9.2	11.4	18.6	70	kg	EPA 2009	body weight
AT	ED x 365				days	EPA 1989	Averaging time - noncarcinogens
IR (Beet Leaf)	0.000092	0	0.018042	0.021	kg/day	EPA 2009	Mean consumer only intake (body weight adjusted) Tables 9-6 from EPA 2011; Beet value
IR (Green Lettuce)	0.003128	0.00798	0.014508	0.0301	kg/day	EPA 2009	Mean consumer only intake (body weight adjusted) Tables 9-6 from EPA 2011; Lettuce value
IR (Red Lettuce)	0.003128	0.00798	0.014508	0.0301	kg/day	EPA 2009	Mean consumer only intake (body weight adjusted) Tables 9-6 from EPA 2011; Lettuce value
EF	350	350	350	350	day/year	EPA 1991	residential exposure frequency
ED	1	2	3	30	year	EPA 1991	residential exposure duration

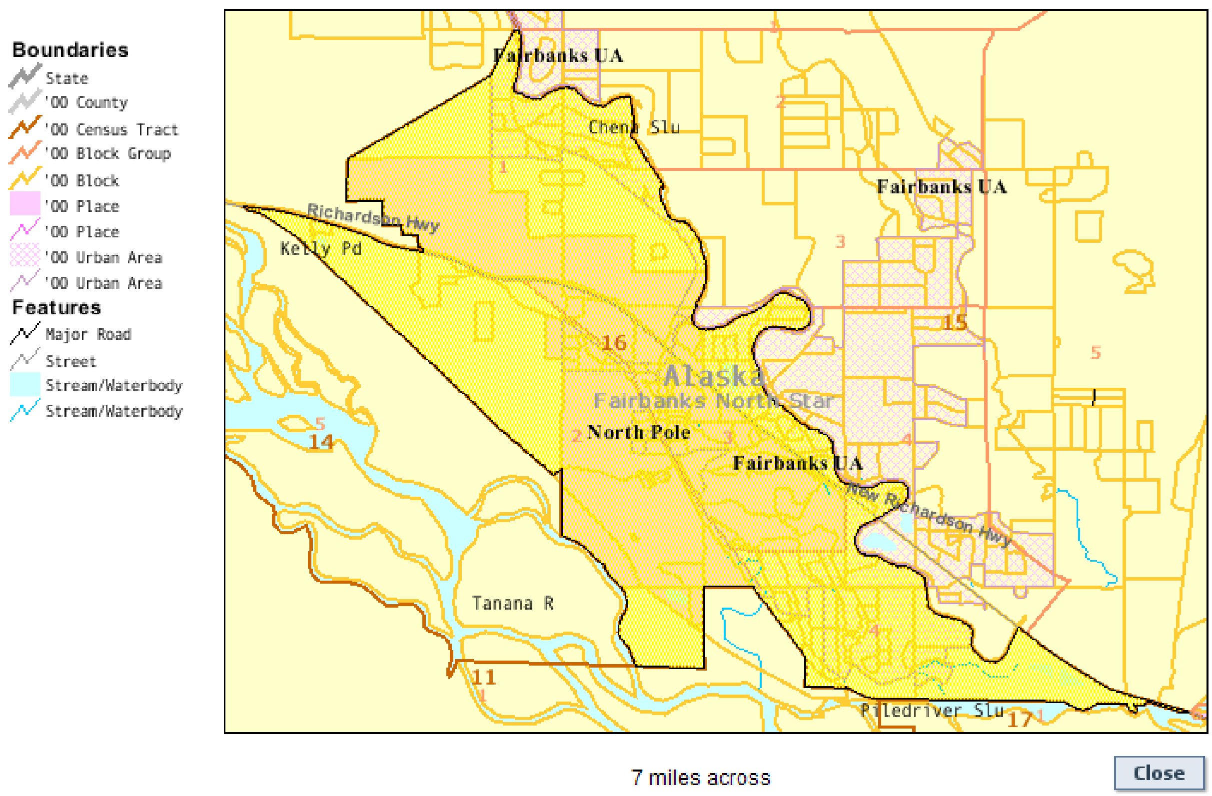
Note: Conservatively assumes all vegetables consumed from home grown produce.

Reference:
United States Environmental Protection Agency. 2011. Exposure Factors Handbook. EPA 600/R-09/052F.

Table 3: Calculated Exposure Dose (mg/kg-d)					
Vegetable (concentration)	**Infant**	**Toddler**	**Child**	**Adult**	**ATSDR Oral Dose**
Beet Leaf (198 ppb)	0.000002	0.000000	0.000184	0.000057	0.0020
Green Lettuce (92.8 ppb)	0.000030	0.000062	0.000069	0.000038	0.0020
Red Lettuce (64.8 ppb)	0.000021	0.000043	0.000048	0.000027	0.0020

Appendix C: Cancer Analysis[7]

Census Tract 16, Fairbanks North Star Borough, Alaska



Geocoding Cancer Cases

The Alaska Cancer Registry database was searched for reportable malignant cancer cases for North Pole and 500 cases were found during the period 1996 to 2009. To determine the observed number of cancer cases for this analysis, we need to identify which cases for North Pole fall within Census Tract 16. For this process, we used a geocoding computer program called MapInfo MapMarker. The program reads an input file of addresses and outputs a file that includes the latitude, longitude, and census tract of each record. The addresses of the 500 cancer cases were loaded into MapMarker and processed. As a result, 371 cases were properly geocoded. However, 47 cases could not be geocoded due to incorrect addresses. These cases needed to be individually researched for correct addresses. There were also 82 cases that were post office (PO) box addresses and so could not be correctly associated with a place of residence. These cases also needed to be individually researched for correct addresses. A total of 124 cases were identified as belonging to Census Tract 16. There was one case that could not be geocoded and two cases with PO box addresses that could not be linked with a place of residence. For this analysis, we assumed that these cases belonged to Census Tract 16, for a total of 127 cases. Next, we determined the population of Census Tract 16 by age so that we could calculate the expected

[7] Analysis conducted by David O'Brien, PhD, Alaska Cancer Prevention and Control Program, Alaska Cancer Registry, Alaska Division of Public Health.

number of cases from 1996-2007, the 12-year period covered by the ACR database. This information was obtained from the 2000 U.S. Census. We used the indirect age-adjustment method to make this calculation and came up with 117 cases, rounded to the nearest whole number.

Expected Number of Cases

The indirect age-adjustment method was used to determine the expected number of cancer cases for the Fairbanks North Star Borough's (FNSB) Census Tract 16. Age-specific rates were calculated for 18 individual age strata for the State Alaska. The Census Tract 16 population for each stratum was obtained from the 2000 US Census. The expected number of cases for each age stratum was calculated using a proportion:

$$\frac{\text{Alaska incidence rate}}{\text{100,000 people}} = \frac{\text{Expected number of cases}}{\text{Census tract population}}$$

The following table summarizes this calculation:

Age Category	AK Incid Rate, 1996-2007	Census Tract 16 Population, 2000 US Census	Expected No. of Cases
00-04 years	29.8	269	0.080162
05-09 years	9.7	308	0.029876
10-14 years	9.8	374	0.036652
15-19 years	18.1	304	0.055024
20-24 years	33.2	321	0.106572
25-29 years	58.6	311	0.182246
30-34 years	78.7	279	0.219573
35-39 years	120.4	341	0.410564
40-44 years	201.4	344	0.692816
45-49 years	339.1	278	0.942698
50-54 years	542.5	225	1.220625
55-59 years	841.5	158	1.32957
60-64 years	1,337.4	95	1.27053
65-69 years	1,918.1	59	1.131679
70-74 years	2,381.7	31	0.738327

75-79 years	2,679.6	36	0.964656
80-84 years	2,672.0	8	0.21376
85+ years	2,241.7	6	0.134502
TOTAL		3,747	9.759832
Observed over 12 years			127
Expected over 12 years			117.118

Standard Incidence Ratio (SIR)

The SIR is calculated as follows:

$$SIR = \frac{\text{Observed number of cases}}{\text{Expected number of cases}} \times 100$$

$$= \frac{127}{117.1180} \times 100 = 108.4377$$

The upper and lower confidence intervals (CI) for the SIR are calculated as follows:
CI = SIR ± (1.96 x Standard Error)

$$\text{Where: Standard Error} = \frac{\text{SIR}}{\text{Square root [number of observed cases]}}$$

$$= \frac{108.4377}{\text{Square root [127]}} = \frac{108.4377}{11.269}$$

$$= 9.6223$$

To calculate the upper and lower CI:

$$CI = 108.4377 \pm (1.96 \text{ X } 9.6223)$$

$$= 108.4377 \pm 18.8597$$

Lower CI = 108.4377 + 18.8597 = 89.5780
Upper CI = 108.4377 – 18.8597 = 127.2973