Taft/

Taft Stettinius & Hollister LLP
425 Walnut Street, Suite 1800 / Cincinnati, OH 45202-3957 / Tel: 513.381.2838 / Fax: 513.381.0205 / www.taftlaw.com
Cincinnati / Cleveland / Columbus / Dayton / Indianapolis / Northern Kentucky / Phoenix / Beijing

FYI-0809-001378
AR226-3910

ROBERT A. BILOTT
513.357.9638
bilott@taftlaw.com

August 13, 2009

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428, Attn: Section 8(e) & FYI
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: Submission To TSCA 8(e)/FYI Database Re: PFOA/PFOS

To TSCA 8(e)/FYI Database:

We are hereby providing the following information for inclusion in the TSCA 8(e)/ FYI databases with respect to PFOA/PFOS:

1. Minnesota Department of Health, "East Metro Perfluorochemical Biomonitoring Pilot Project" (July 21, 2009).

Very truly yours,

Robert A. Bilott / mdm

Robert A. Bilott

RAB:mdm
Enclosure

CONTAINS NO CBI

Contains No CBI

321213

11483510.1

[redacted]

Taft Stettinius & Hollister LLP
425 Walnut Street, Suite 1800
Cincinnati, Ohio 45202-3957

TAFT STETTINIUS & HOLLISTER LLP
ROBERT A. BILOTT

TSCA Confidential Business Information Center
(7407M)
EPA East - Room 6428, Attn: Section 8(e) & FYI
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

MN EPHT
Environment, Exposure & Health

Minnesota
Environmental
Public Health
Tracking

East Metro Perfluorochemical Biomonitoring Pilot Project

Minnesota Department of Health

July 21, 2009

MINNESOTA MDH DEPARTMENT OF HEALTH

Commissioner's Office
625 Robert Street N
P.O. Box 64975
St. Paul, MN 55164-0882
651-201-5000
www.health.state.mn.us

MN EPHT
Environment, Exposure & Health

Minnesota
Environmental
Public Health
Tracking

East Metro Perfluorochemical Biomonitoring Pilot Project

July 21, 2009

For more information, contact:
Environmental Health Tracking & Biomonitoring Program
Chronic Disease and Environmental Epidemiology Section
Health Promotion and Chronic Disease Division
Minnesota Department of Health
85 East Seventh Place, Suite 220
P.O. Box 64882
St. Paul, MN 55164-0882

Phone: 651-201-5000
Fax: 651-201-5898
TDD: 651-201-5797

Upon request, this material will be made available in an alternative format such as large print, Braille or cassette tape. Printed on recycled paper. This report is also available online at www.health.state.mn.us/tracking.

ACKNOWLEDGEMENTS

MINNESOTA DEPARTMENT OF HEALTH
Sanne Magnan, MD, PhD, Commissioner
Jeanne M. Danaher, JD, Deputy Commissioner

Minnesota Environmental Health Tracking and Biomonitoring Steering Committee

John Linc Stine, Assistant Commissioner of Health
Joanne Bartkus, PhD, Director, Public Health Laboratory Division
Linda B Bruemmer, MS, MPA, Director, Environmental Health Division
Mary Manning, RD, MBA, Director, Health Promotion and Chronic Disease Division

Minnesota Environmental Health Tracking and Biomonitoring Advisory Panel

John Adgate, PhD
Bruce Alexander, PhD
Beth Baker, MD, MPH
Alan Bender, DVM, PhD
Cecilia Martinez, PhD
Debra McGovern
Jill Heins Nesvold, MS
Geary Olsen, DVM, PhD
Susan Palchick, PhD, MPH
Gregory Pratt, PhD
Dan Stoddard, MS, PG
David Wallinga, MD (former member)
Samuel Yamin, MPH
Lisa Yost, MPH, DABT

Minnesota Environmental Health Tracking and Biomonitoring Workgroup

Jerome Alholm
Michonne Bertrand, MPH
Jean Johnson, PhD, MS
Frank Kohlasch, JD
Louise Liao, PhD
Rita Messing, PhD
Pamela Shubat, PhD
John Soler, MS
Allan Williams, PhD, MPH
Erik Zabel, PhD
Joe Zachmann, PhD

Report authors:
Adrienne Kari, MPH, Jean Johnson, PhD, MS, and Allan Williams, MPH, PhD,
Division of Health Promotion and Chronic Disease
Carin Huset, PhD, Public Health Laboratory Division

Sincere thanks to our project personnel, Kathy Morseth, for all her hard work recruiting, enrolling, and interviewing participants for the East Metro biomonitoring pilot project. We also gratefully acknowledge Medical Consultant, Mary Winnett, MD, MPH, for her work providing education to area clinicians and medical counseling with participants and their physicians. Thanks to many other department staff for their contributions: Michonne Bertrand, Tannie Eshenaur, Mary Jeanne Levitt, Jeannette Sample, Leslie Schreier and Paul Swedenborg. Finally, we thank the many project participants and members of the East Metro community for their time, participation and support.

For more information contact:
Jean Johnson
Minnesota Department of Health
Division of Health Promotion and Chronic Disease
651-201-5902 or email: jean.johnson@state.mn.us

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

EXECUTIVE SUMMARY

In 2007 the Minnesota Legislature enacted legislation directing the Minnesota Department of Health (MDH) to complete a series of biomonitoring pilot projects. These projects were directed and implemented to provide MDH with the experience and knowledge to create a state biomonitoring program by building both laboratory and epidemiological capacities. One of these projects was to investigate the range and distribution of perfluorinated chemicals (PFCs) in 100 individuals from each of two communities likely to have been exposed.

Perfluorochemical contamination of private and municipal drinking water wells in Washington County, east of the Minneapolis-St. Paul metropolitan area (also referred to as "East Metro"), was first discovered in 2004 during an assessment of ground water contamination from nearby waste disposal facilities by the Minnesota Pollution Control Agency (MPCA) and MDH[1]. Drinking water supplies were analyzed for seven types of PFCs contaminants including but not limited to perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS), and perfluorobutanoic acid (PFBA).

MDH selected two Washington County East Metro communities, Oakdale Municipal Water Supply recipients and private well owners in Lake Elmo and Cottage Grove with known contamination, to conduct the East Metro PFC Biomonitoring Pilot Project. MDH defined these communities by drinking water source as follows:

1. People currently living in households in Lake Elmo and Cottage Grove with a private well with PFOA and/or PFOS contamination above trace levels (>0.01 ppb) in at least one well water sample, and
2. People currently living in households served by the Oakdale Municipal Water Supply.

In the municipal water community (Oakdale), 500 homes were randomly selected from the municipal water billing records to receive a household survey to identify eligible adults living in the household. For the private well water community (Lake Elmo/Cottage Grove), all 169 homes identified with contaminated wells received the household survey. Eligible individuals were defined as household residents over 20 years of age living in the home prior to Jan. 1, 2005.

From the survey respondents in each community, a list of eligible residents was compiled and 100 people were randomly selected and invited to participate. If anyone declined participation, a replacement individual was randomly selected. The project required participants to provide a single 20 cc blood draw at a local clinic and answer a short telephone survey. Specimens were collected from October 2008 through January 2009. At the conclusion of the project 98 people from each community had completed all of the project requirements for a total of 196 participants. Project protocols were reviewed by the Environmental Health Tracking and Biomonitoring (EHTB) Advisory Panel, presented to the community at public meetings for community acceptance, and approved by the MDH Institutional Review Board.

Age and length of residence in the home were comparable among participants from the two communities. In both communities, the average age of the participants was 53 years (range 20-86). The average length of residence in the home was 18 years (range 4-62) in Oakdale and 20 years (range 4-60) in Lake Elmo and Cottage Grove. In both communities, more females (n=108) than males participated (n=88).

The blood specimens provided by participants were collected at 2 local clinics according to protocol and brought to the MDH Public Health Laboratory (PHL), where each specimen was analyzed for the 7 PFCs previously analyzed for in water. Analytical methods used were developed and based on methods utilized by the CDC for the National Health and Nutrition Examination Survey (NHANES). Of the 7 types of PFCs analyzed for in the 196 blood specimens; 3 PFCs (PFOA, PFOS, and PFHxs) were detected in all specimens, 1 PFC (PFBA) was detected in 55 specimens (28%), 1 PFC (PFBS) was detected in 5 specimens (3%), and the final 2 types of PFCs (PFPeA and PFHxA) were below the limit of detection (0.1 ng/mL) for all 196 specimens.

Concentrations of PFOA, PFOS, and PFHxS in the population sample were log-normally distributed and geometric means were calculated. Levels did not differ significantly between the two communities. In the combined communities, PFOA had a geometric mean of 15.4 ppb (range 1.6-177ppb), PFOS had a geometric mean of 35.9 ppb (range 3.2-448 ppb), and PFHxS had a geometric mean of 8.4 ppb (range 0.32-316 ppb). As with most other studies, mean levels

for PFOA, PFOS, and PFHxS were found to be higher in males than females and increased with age. These PFC levels were also highly correlated with each other. Increasing length of residence in the home was found to be positively associated with PFOA and PFHxS, but not PFOS.

PFC levels found in the 196 adults from the two communities were moderately elevated in comparison with results reported for the US general population[2] but comparable to or lower than levels found in other studies of communities exposed via drinking water. However, comparisons with other general population and community studies are difficult to interpret due to differing population characteristics and time periods involved. 3M ceased production of ammonium PFOA in 2000 and as a result general population levels have been declining[3]. Consequently, PFC levels will be expected to vary in populations when tested during different time periods. As expected, community levels found in this study were much lower than levels found in occupational studies of PFC manufacturing workers.

Additional analysis of these findings along with analyses of drinking water PFC contaminant levels and community PFC serum levels will be completed in a follow up to this report. Any further determination of routes and sources of exposure would require a more extensive investigation and was beyond the scope of this pilot project. MDH staff will present these findings to the community and solicit recommendations from the community for further public health action in response to the project results.

The Environmental Health Tracking and Biomonitoring Science Advisory Panel recommended on June 2, 2009 after viewing of the pilot project preliminary data, that follow up biomonitoring be completed at a later date with these same communities to measure change in levels over time. Blood levels of PFCs in the population are expected to decrease due to the actions that have been taken to remove PFC from the drinking water in these communities.

The purpose and intent of this pilot project was to inform a future biomonitoring program for the state of Minnesota. The project succeeded in this respect and the information and experience it provided are necessary and valuable to the success of the Environmental Health Tracking and Biomonitoring program at MDH.

INTRODUCTION

In 2007 the Minnesota State Legislature passed Minnesota Statute 144.995 – 144.998, which established the Environmental Health Tracking and Biomonitoring (EHTB) program and directed the Minnesota Department of Health (MDH) to design and implement four pilot biomonitoring projects. The primary purpose of each of the pilot projects is to measure the range and distribution of a selected chemical or chemicals, in the body, in a community identified as likely to be exposed. Exposure is measured through the collection of a biological sample, such as blood or urine, from voluntary participants from the community. Another purpose of the pilot projects is to build biomonitoring capacity in the state and to develop recommendations for the Legislature for the creation of an ongoing biomonitoring program in Minnesota.

This biomonitoring pilot project, known as the East Metro PFC Biomonitoring Pilot Project, was designed to measure the range and distribution of 7 types of perfluorinated chemicals (PFCs) in 100 individuals from each of two separate communities.

Contamination of drinking water supplies with PFCs in the east metro was discovered in the summer of 2004. MPCA and MDH collected water samples from private well owners as well as the Oakdale Municipal supply to assess and define the extent of the contamination. Routine monitoring was established by MDH and MPCA and actions to stop drinking water exposure were taken, including the provision of bottled water, granular activated carbon (GAC) home filters, access to municipal water, and a water treatment plant that utilizes large GAC filters to remove PFCs for the Oakdale Municipal Water Supply[1]. With the implementation of these filtration practices, drinking water exposure in the community has been reduced to below established health-based values, and the plan for remediation of the contaminated waste facilities are currently underway which may further reduce the PFC exposure through drinking water.

EHTB program staff, with input from the EHTB Advisory Panel and an interagency workgroup, developed a project protocol for the East Metro PFC Biomonitoring Pilot Project. The target sample size of 100 individuals from each of two exposed communities was specified in the legislation. The project was presented to the community in community group meetings and with

local public health officials for community acceptance. The project was also reviewed and approved by the MDH Institutional Review Board (IRB) for the protection of human subjects in research.

METHODS

Participant Recruitment and Informed Consent

Figure 1 summarizes the recruitment and participation of study subjects from the contaminated Municipal water supply community (Oakdale). To recruit individuals who consumed water from the Oakdale Municipal Water supply, the billing addresses of all the households receiving water service prior to Jan. 1, 2005 were provided to EHTB and included a total 6,655 households. A random sample of 500 households was selected from that list to receive a household survey. The survey asked one individual in each household to identify all adults, over the age of 20, currently living in the home who had lived there prior to Jan. 1, 2005. The household survey also asked individuals to identify the current drinking water source utilized in their home, if any filtration device was used, the gender, the birth date, and length of residence in the home for each adult. These descriptive characteristics for each community are described on Tables 1 and 2. From the surveys returned to EHTB a second list was compiled of all the eligible adults identified on the household surveys. From this list, 100 people were randomly selected and invited to participate in the study. Individuals were mailed information about the study and an informed consent document to be returned by mail. If an individual declined to participate another person was randomly selected from the list as a replacement. In total, 154 individuals were invited to participate, 100 consented, and 98 completed all the project requirements by the project end date.

Figure 2 describes the recruitment and enrollment process of the 100 individuals from the community with contaminated private wells (Lake Elmo/Cottage Grove). To recruit individuals who consumed water from private wells with PFC contamination, a list of addresses was provided to EHTB from MDH well sampling records of households with private wells with a PFOS or PFOA level greater than 0.1 ppb (trace levels). These 169 homes were then sent the household survey asking them to identify adults, over the age of 20, currently residing in the home that had lived there prior to Jan. 1, 2005. From the list of eligible adults, 100 were

randomly selected and invited to participate. Information and a consent form were mailed to the home. If an individual chose not to participate, a replacement was randomly selected from the list. A total of 149 individuals were invited to participate, 102 consented, and 98 completed all project requirements by the project end date.

Once the signed consent materials had been received by project personnel, the participant was contacted by telephone to complete a short interview and given an opportunity to ask questions about the project. Each participant was asked in the telephone interview about current drinking water habits, pregnancy status for females, general health and about current or previous employment at 3M so that possible occupational exposures could be identified and accounted for in the analyses. Participants were then sent instructions to visit one of two local health clinics contracted to conduct the blood draw and processing for the project.

Specimen Collection

Participants had a choice of visiting the Health East Woodbury or Oakdale clinic to provide a blood specimen. Specimens were collected from consenting participants by venipuncture into red-topped (serum) tubes at the local clinics. Included with the instructions to the participant were a set of participant ID labels to be affixed to the blood draw tubes. By attaching the individual participant ID number to the blood draw tube, the specimen was de-identified before arrival at the MDH Public Health Laboratory (PHL). No private information on individuals in the study was collected either at the clinic or at the PHL. After collection, blood was allowed to clot, and tubes were centrifuged to separate serum and red blood cells. Serum was aliquoted into cryogenic vials and then frozen. Samples were delivered to the MDH PHL frozen and stored in a locked, ultralow (-80°C) freezer until analysis.

Laboratory Analyses

Fluorochemical standards, perfluorbutanoate, perfluoropentanoate, perfluorohexanoate, perfluorooctanoate, potassium perfluorobutane sulfonate, sodium perfluorohexane sulfonate and potassium perfluorooctane sulfonate were purchased from Wellington Laboratories (Wellington Laboratories, Guelph, Ontario, Canada). Internal standards, perfluoro-n-[1,2,3,4-$^{13}C_4$]butanoic acid, perfluoro-n-[1,2-$^{13}C_2$]hexanoic acid, perfluoro-n-[1,2,3,4-$^{13}C_4$]octanoic acid, perfluoro-1-

hexane[$^{18}O_2$]sulfonate, and perfluoro-1-[1,2,3,4-$^{13}C_4$]octane sulfonate were also purchased from Wellington Laboratories. Standards were >98% pure and consisted of 98.5-100% linear isomers. Acetonitrile, formic acid, methanol and ammonium hydroxide were purchased from Fisher (Fisher Scientific, Pittsburgh, PA) See Table 3. Gibco newborn bovine calf serum was purchased from Invitrogen (Invitrogen Corporation, Carlsbad, CA) for matrix matched calibration curves. Solid phase extraction (SPE) cartridges were purchased from Waters (Waters Corporation, Milford, MA).

The method employed for extraction followed that published by Kuklenyik et al[4] with some modifications which are described below. Unknown samples and standards were prepared in the same way; specimens were thawed, and a one ml aliquot was added to a polypropylene test tube, diluted with 3 mL 0.1M formic acid, spiked with 50 uL of a stock solution containing internal standard (for unknown samples) or internal standard and analyte solution (for calibration curve, and QC samples) and mixed on a vortex mixer. Stock solutions were prepared such that a 50 uL spike into 1 mL of serum yielded concentrations of 0.05 – 50 ppb for analytes and 0.75 ppb for internal standards. Sample extractions were performed manually on a 24 port vacuum manifold using Oasis HLB SPE cartridges. Cartridges were conditioned with methanol, acetonitrile and 0.1M formic acid. Samples were loaded and allowed to pass through at a dropwise rate, and then washed twice with 3.0 mL 0.1M formic acid and once with 1.0 mL 1% ammonium hydroxide in water. Cartridges were eluted into polypropylene test tubes with 1.0 ml 1% ammonium hydroxide in acetonitrile and concentrated under nitrogen to 100 µL. Samples were reconstituted with 200 µL 0.1% formic acid in 25% acetonitrile and 75% water and transferred to autosampler vials.

Method accuracy and precision were determined by spike and recovery experiments. Four aliquots of bovine calf serum (1 mL each) were spiked at 10 ng/mL and extracted as described above. The experiment was repeated at a 1 ng/mL spike level. The accuracy and precision of the method as determined by these spike and recovery experiments is described in terms of % Recovery and %RSD (relative standard deviation) and can be found in Table 4. To determine the method detection limit (MDL), seven replicates of serum were prepared at a concentration 2 to 5 times the noise level and extracted as described above. The MDL was calculated by

multiplying the standard deviation of the replicates by the students t value at 99% confidence level. Method detection limits for the analysis of these PFCs in serum are found in Table 5. The report level for method is higher than the MDL and is the value of the lowest point on the calibration curve.

Ongoing quality control samples prepared and extracted with each batch of samples included a method blank (bovine calf serum spiked with internal standard), a calibration verification standard (CVS) (bovine calf serum spiked with internal standard and analytes), a matrix spike (an unknown sample spiked with internal standard and analytes), and a duplicate (a duplicate of an unknown sample). Any analyte peaks in the method blank must be < ½ the report level or the extraction must be repeated on the entire batch. The CVS recovery must be within 80 to 120% for all analytes or the samples will be flagged for reanalysis. The recovery for the matrix spike would be within 30% of its theoretical value; failure to meet this criteria suggests matrix interference, in which case the sample should be diluted and reanalyzed. The precision of the unknown duplicate samples must be < 20% relative percent deviation.

Sample analysis was performed with an Agilent 1200 HPLC (Agilent Technologies, Santa Clara, CA) with a Betasil C_8 3 µm, 2.1 x 5 mm column, and a Betasil C_8 5 µm, 3 x 50 mm precolumn, both from Thermo (Thermo Fisher Scientific, Waltham, MA) between the pump and the autosampler. Sample extracts were injected (10 µL) and analytes separated using the gradient outlined in Table 6 with 0.1% formic acid in water (solvent A) and 0.1% formic acid in acetonitrile (solvent B). The HPLC was coupled to an Applied Biosystems QTrap 4000 tandem mass spectrometer (Applied Biosystems Inc., Foster City, CA). Acquisition parameters and ion transitions monitored are listed in Table 7. Quantitation was performed using 8 point calibration curves prepared daily with bovine calf serum and spiked standard and internal standard solutions. Calibration curves were linear with $r^2 \geq 0.99$ and weighted 1/x. Samples with concentrations higher than the highest point in the calibration curve were diluted as necessary.

Data Analyses

All questionnaire data were double entered and edit checked for errors. Statistical analysis of the PFC serum concentrations was completed using SAS 9.1. Geometric means and log transformations were determined for PFOA, PFOS, and PFHxS as each had log normal distributions. The skew in these distributions is not unusual and most likely due to a few elevated measures in the project group.

RESULTS

Demographic Characteristics of Participants

Tables 8 and 9 describe the demographic characteristics of the 196 participants that completed the East Metro PFC Biomonitoring Pilot Project. The average age for the 98 participants comprising the municipal water supply community and the 98 in the private well water community was 53 years of age. The average length of residence in the home for participants in the Oakdale municipal water and Lake Elmo/Cottage Grove private well water communities was 18 and 20 years, respectively. In each community, 44 participants were male and 54 were female. A total of 30 individuals out of the 196 participants were current or former employees of 3M, with 3 identifying work in either PFC production or research and 1 identifying work in both. Of the 196 participants 187 (95%) reported their race/ethnicity as non-Hispanic white, 1 (0.5%) as Hispanic, 3 (2%) as Asian American, 1 (.5%) as Native American, and 4 (2%) identified as other. A total of 97 (50%) described their health as very good, 93 (47%) described it as good, 6 (3%) described it as bad, and 0 (0%) described it as very bad.

PFC Serum Levels: Distributions and Geometric Means

Tables 10 - 14 and Figures 3 – 11 display the distribution for each PFC serum concentration. All 196 samples were analyzed for 7 PFCs; PFOA, PFOS, PFHxS, PFBA, PFBS, PFPeA, and PFHxA (see Table 3 for definitions of PFC chemical acronyms). PFOA had a geometric mean of 15.4 ng/mL (ppb), a range of 1.6 - 177 ng/mL, and a median of 16 ng/mL in the combined communities. In the private well water community the geometric mean was 13.6 ng/mL, with a range of 1.6 – 177 ng/mL, and a median of 13 ng/mL. The municipal water supply community

had a PFOA geometric mean of 17.3 ng/mL, a range of 2 – 79 ng/mL, and a median of 21 ng/mL.

The geometric mean of PFOS in the combined communities was 35.9 ng/mL, with a range of 3.2 – 448 ng/mL, and a median of 41 ng/mL. In the private well water community the geometric mean was 32.9 ng/mL, with a range of 3.2 – 448 ng/mL, and a median of 35 ng/mL. The municipal water supply community had a PFOS geometric mean of 39.3 ng/mL, a range of 3.9 – 166 ng/mL, and a median of 43 ng/mL.

The third PFC analyte PFHxS had a geometric mean of 8.4 ng/mL, a range of .32 – 316 ng/mL, and a median of 8.9 ng/mL in the combined communities. In the private well water community the geometric mean was 8.3 ng/mL, with a range of .37 – 316 ng/mL, and a median of 7.5 ng/mL. The municipal water supply community had a PFHxS geometric mean of 8.6 ng/mL, a range of .32 – 72 ng/mL, and a median of 9.8 ng/mL.

PFBA was detected in 55 (28%) of the 196 serum samples collected from the project population (PFBA level of detection (LOD) was 0.1 ng/mL). PFBS was detected in 5 (3%) of the 196 serum samples collected from the population (PFBS LOD was 0.1 ng/mL). With so many of the samples measuring below the LOD, imputation of these values is not recommended for calculation of a geometric mean or other measures of central tendancy[5]. PFPeA and PFHxA were not detected in any of the 196 serum samples collected.

PFC Levels by Gender, Age, Length of Residence, Community and Employer Status

Previous biomonitoring studies have found differences in PFC serum concentrations based upon gender[2, 6], therefore basic analyses were completed using t-test statistics to determine whether observed differences between groups in mean serum PFCs are statistically significant. These comparisons were only completed with PFOA, PFOS, and PFHxS as these perfluorochemicals were above the level of detection for all 196 samples. To complete these analyses each of the PFC measures were log transformed for normality. Figures 12 – 14 depict the log transformed variables.

Tables 15 summarizes the findings comparing geometric mean serum PFC levels by gender. Mean serum PFCs were significantly higher in males than females for PFOS ($p = 0.001$) and for PFHxS ($p = 0.004$), consistent with other study results both in another community exposed to contaminated drinking water and in the general population[2, 6-8], but no gender difference was found for PFOA exposure.

Simple linear regressions were run to examine the relationships between PFC serum levels and age; scatterplots of these relationships are presented in Figures 15 – 17. For the relationship between PFOA and age, $R^2 = .11$ ($p \leq .0001$), for the relationship between PFOS and age, $R^2 = .08$ ($p < .0001$) and for the relationship between PFHxS and age, $R^2 = .10$ ($p < .0001$).

To further investigate this relationship, age was divided into 3 categories: 20 – 39 years (N = 19), 40 – 59 years (N = 106), and ≥60 years (N = 71), the same age categories NHANES has chosen to use in recent publications detailing PFC levels in the general population[7, 8]. To determine which groups were different from one another and the group with the highest PFC serum levels, a Tukey's test was performed. PFOA was found to be significantly different ($p< 0.05$) across all three age categories, with those in the ≥60 years category having the highest mean PFOA level. These results are displayed in Figure 18.

Figure 19 displays the results for the comparison of mean PFOS serum levels across the three age categories. Comparison of mean PFOS serum levels across age categories demonstrates that those in the ≥60 years category are significantly different ($p<0.05$) than those in the 20 39 years. Those in the 40 59 years category were also found to be different than the 20 39 years category ($p<0.05$). However those in the 40 59 years category were not found to be significantly different from those in the ≥60 category. Those in the oldest age category, ≥60 years, were found to have the highest mean PFOS serum concentration.

The difference in mean PFHxS serum levels across age categories was similar to the pattern seen for PFOA. As shown in Figure 20, those in the ≥60 years category were found to be significantly higher ($p<0$ .05 level) when compared to both the 40 59 years, and 20 39 years

categories. A significant difference was also observed between those in the 40 59 years category and those in the 20 39 years category.

Simple linear regression models were run to investigate the relationship between length of residence and PFOA, PFOS, and PFHxS; scatterplots of these relationships are presented in Figures 21 - 23. Significant associations were found between length of residence and PFOA (R^2= .09, p <0.0001) and length of residence and PFHxS (R^2= .07, p = 0.0003), but not between PFOS and length of residence (R^2= .02, p = 0.069). To complete further analyses, the length of residence was divided into 4 categories; 4 – 9 years (N = 49), 10 – 19 years (N = 71), 20 – 29 years (N = 36), and greater than 30 years of residence (N = 39).

After comparison of the mean PFOA serum level across the 4 length of residence categories with the Tukey's test, those in the highest length of residence category, ≥30 years, and those in the 10 19 years category were found to be significantly different from those in the shortest length of residence category, 4 – 9 years. Those in the category with the longest length of residence, ≥30 years, were found to have the highest mean PFOA serum concentration. These relationships are displayed in Figure 24.

Figure 25 depicts the relationship between the mean PFHxS serum concentration and the 4 length of residence categories. The analyses of the length of residence categories and the length of residence categories found that those in the longest length of residence, ≥30 years, had a mean PFHxS serum concentration significantly different ($p<0.05$) than those in the shortest length of residence, 4 9 years. No other category was found to have a significantly different mean PFHxS serum concentration than another category. Those with a length of residence ≥30 years were found to have the highest mean PFHxS serum concentration.

Although the simple analyses found the relationship between PFOS and length of residence to be non-significant, Tukey's tests for mean PFOS and categories of length of residence were also performed for PFOS. No significant differences were found in the mean PFOS serum concentrations across the 4 categories for length of residence, as is shown in Figure 26.

Table 16 describes the analyses completed to compare the municipal water supply community to the private well water community. No difference was found between the two communities in regards to age or length of residence. A borderline significant result ($p = .06$) was found when comparing the mean PFOA serum concentrations between the two communities (well water community 13.6 ng/mL and municipal water community 17.3 ng/mL). The mean PFOS serum concentration level and the PFHxS serum concentration level were not found to be significantly different between the two communities.

Of the 196 participants, 30 reported in the telephone interview that they were current or former 3M employees. Analyses to determine if there were differences between those with a 3M employment history and those without were performed as shown in Table 17. The first test found that those in the 3M work group were significantly older than those not in the 3M work group: workers had an average age of 59 years and non workers had an average age of 52.5 years ($p=0.001$). Similar to the entire project sample there were more female workers (18) than male workers (12) participating in the pilot project. No significant difference was found between the two groups in regards to length of residence nor the number of years one had lived in Oakdale (municipal water group). Observed differences in PFC serum levels between current or former workers and non-workers were non-significant for PFOA ($p = 0.52$) and borderline significant for PFOS ($p = 0.07$) with the mean PFOS serum level for 3M workers at 45.5 ng/mL compared to 34.5 ng/mL for non-3M workers. The mean PFHxS serum concentration was significantly different between the two groups ($p = 0.003$): the mean concentration was 12.4 ng/mL for workers and 7.9 ng/mL for non-workers. Age may account for some of the differences seen in these two sub groups as the worker group was significantly older than the non-worker group and age has demonstrated an association with higher PFC serum levels.

Age and length of residence were both associated, to differing degrees, with the PFC serum concentrations. However, age and length of residence are also strongly correlated with each other (a situation referred to as collinearity), creating difficulties in interpreting which factor is most important. While both measures are considered indicators of the duration of exposure to contaminated drinking water, age may potentially reflect other past sources of exposure to PFCs such as diet and various consumer products.

Communication of Individual Participant Results

Each participant was asked during the informed consent process to decide if they would like to receive the results of the test, and all participants requested that the results be provided to them. Each participant was sent a letter with their individual PFC serum concentrations in comparison with the PFC serum concentrations (geometric mean and range) published by the National Health and Nutrition Examination Survey (NHANES), a population-based sample of the US general population for the 2003 – 2004 sample years. A booklet was included with each letter to provide more information on a number of common questions and topics including: what are PFCs, what individual's PFC levels mean, PFC research both for health and exposure, information on cancer rates in Dakota and Washington counties, methods to avoid PFC exposure, and information on labs that will provide analysis of serum for PFCs.

Case Descriptions

MDH staff examined interview information collected on the three individuals who had the highest measured concentrations of PFCs to describe their characteristics as shown below:

- Case #1 – PFOA (177 ng/mL) and PFOS (448 ng/mL)
  The individual with the highest PFOA measure similarly had the highest PFOS measure. This individual is male, in the oldest age category (≥60 years), in the second length of residence category (10 to 19 years), and is a member of the private well water community. This individual is not a current or former 3M employee, non-Hispanic white, and describes his health as very good.

- Case # 2 – PFHxS (316 ng/mL)
  This individual is female, in the oldest age category (≥60 years), in the longest length of residence category (≥30 years), and is a member of the private well water community. This individual is not a current or former 3M employee, non-Hispanic white, and describes her health as good.

- Case #3 – PFBA (8.5 ng/mL)

This individual is female, in the oldest age category (≥60 years), in the longest length of residence category (≥30 years), and is a member of the municipal water supply community. This individual is a current or former 3M employee (though never a PFC research or production employee), non-Hispanic white, and describes her health as good.

Comparison of Community Findings with Other Studies of Population PFC Serum Levels

Comparisons of the East Metro community findings with other published reports of PFC serum levels are helpful in interpreting these findings (presented in Tables 10-13). Studies of PFC concentrations in human serum have been performed in various populations, countries, and time periods. Some of the most relevant or comparable studies have been chosen for comparison to the East Metro communities, but these studies do not comprise an exhaustive list of all the available biomonitoring data.

NHANES, the National Health and Nutrition Examination Survey, is a continuous survey of the United States general population that began in the early 1960s. Since 1999, a random sample of the population has been selected and examined every 2 years, with participants completing a full physical examination, providing sociodemographic information, a complete medical history, and a blood and urine sample. These blood and urine samples are used to collect physical health information and are then provided to the CDC lab for biomonitoring analysis. For sampling conducted in the 2003 – 2004 survey, the results of completed serum analyses for a select number of PFCs have been published; they include PFOA, PFOS, and PFHxS. In total the NHANES 2003 – 2004 sample size for PFC analysis was 2, 094 individuals, 1,041 females and 1,053 males. The geometric mean PFOA serum concentration for the NHANES sample was 3.9 ng/mL (East Metro was 15.4 ng/mL), the geometric mean PFOS serum concentration was 20.7 ng/mL (East Metro was 35.9 ng/mL), and the geometric mean PFHxS was 1.9 ng/mL^2 (East Metro was 8.4 ng/mL).

These comparisons suggest that the geometric mean serum concentrations for PFOS, PFOA, and PFHxS in the East Metro communities are moderately elevated in comparison to the US general population. A comparison of the ranges of the distributions are very similar, however, indicating

that this difference in the means is not likely due to the influence of a few extremely elevated individuals as might be expected in a community that includes individuals with occupational exposures. Similarly, in both the NHANES sample and the East Metro sample, males were found to have significantly higher levels of PFOA, PFOS, and PFHxS, and strong correlations were found between levels of PFOA, PFOS, and PFHxS [2]. Table 18 displays the correlations between the three PFCs in this project.

A second population for comparison to the East Metro communities are those living in the Ohio River Valley where drinking water contamination with PFOA has been found at higher levels than were measured and recorded in the East Metro area. Through a court settlement, residents in the Ohio River Valley are participating in a large scale epidemiologic investigation (known as the "C8 study) of the PFOA contamination, exposure, and possible health effects. The geometric mean for the Little Hocking water district, the district with the highest level of contamination for samples collected in 2005 - 2006, was approximately 197 ng/mL with a median of 224.1 ng/mL[9]. The serum concentrations seen in the Little Hocking water district are very elevated in comparison to PFOA levels seen in the East Metro. Again, males were found to have a higher mean PFOA serum concentration as were those with increasing age[9].

A project measuring the serum PFC concentrations in 600 plasma samples collected by the Red Cross in 2006 found levels similar to those found by NHANES. The age range for the population, 20 to 69 years of age is similar to that of the East Metro sample. The geometric mean PFOA serum concentration was 3.4 ng/mL, PFOS was 14.5 ng/mL, and PFHxS was 1.5 ng/mL. As has been seen in other biomonitoring studies, males were found to have higher PFC serum concentrations. Unlike previous studies and the East Metro sample, the authors found no differences in PFC concentration across age categories[3].

In 2006 a project was completed in Arnsberg, Germany, measuring levels of PFCs in individuals who had consumed water with known PFC contamination. The measured PFOA water concentrations for the Arnsberg area are similar to those seen in the East Metro, and the time period in which sampling occurred make it a desirable comparison population. The project had 101 men and 164 women participate, the geometric mean PFOA serum concentration was 23.4

ng/mL for women and 25.3 ng/mL for men, PFOS had a geometric mean serum concentration of 5.8 ng/mL for women and 10.5 ng/mL for men, PFHxS had a geometric mean serum concentration of 1.1 ng/mL for women and 2.5 ng/mL for men. The PFOA serum levels for this population had the greatest elevation, though not unexpectedly, as PFOA was the major water contaminant. As has been seen previously and similarly in the East Metro population, males and those of increasing age had the highest PFC serum concentrations[10].

A final and necessary comparison group would be to an occupational cohort. 3M scientists have published a number of studies detailing 3M employees' PFC exposure and looked for associations with a range of health outcomes. A group of 215 3M employees from the Decatur, Alabama, plant had serum collected in 2000 for PFC analysis. The geometric mean PFOA serum concentration for this population was 1,130 ng/mL and PFOS had a geometric mean serum concentration of 440 ng/mL[11]. Both of these PFCs have mean serum concentrations an order of magnitude greater than was seen in the East Metro Biomonitoring Pilot Project sample.

DISCUSSION

The results from this biomonitoring pilot project provide information on the range and distribution of PFOA, PFOS, PFHxS, PFBA, PFBS, PFPeA, and PFHxA in a sample of residents from two communities with previous PFC-contaminated drinking water. Serum PFC levels in these East Metro communities, sampled in 2008, are moderately elevated in comparison to the US general population (NHANES, 2003-2004). This is not unexpected as the NHANES sample is a representation of the United States general population, where as the East Metro sample represents two communities with a known history of PFC drinking water contamination. The East Metro communities in this study may have other important differences that could affect exposure. Because of the eligibility criteria for this project, participants were likely to be older and less transient than the general US population included in NHANES. From the available literature, the distribution of PFC serum concentrations in the project communities are found to be comparable to another population with similar levels of water contamination in Arnsberg, Germany.

The eligibility criteria for participation in this project were driven by the Legislative language, "likely to be exposed". Based on community concern for residents with long term exposure and to include individuals with the highest likelihood of exposure, participants had to be at least 20 years of age, living in one of two communities with known water contamination, and have been a resident prior to Jan. 1, 2005. Filtration devices were installed on drinking water sources after Jan. 1, 2005 to bring PFC levels to below health based values. People moving in to the area after the installation of these devices are unlikely to be exposed to drinking water contamination. The community also requested that children be included in the project. However, ethical considerations and federal guidelines preclude the inclusion of children in research with potential health risk when there is no medical or health benefit to the child. Because the project was designed specifically to select those with the greatest likelihood of exposure, these results should not be interpreted as representing the general population currently living in the East Metro area.

Comparisons between studies published in the scientific literature as a means for interpreting biomonitoring results must be made with caution. Laboratory processes have varying levels of detection such that comparisons based on percentages of detections may not be valid. The time period of sample collection must also be taken into consideration. PFOS, PFOA, and PFHxS have half-lives of 3-8 years, such that the timing of sample collection relative to the exposure will affect the levels. If levels had been measured at an earlier point in time when contamination of the East Metro water first occurred, higher levels may have been observed. Levels in the general population, last reported for samples collected in 2003-04, are likely to be lower in 2008. In the absence of a concurrently monitored comparison population without a history of water contamination, these comparisons with the published literature are helpful but should be interpreted cautiously.

The levels found in the NHANES population demonstrate that there is widespread exposure to PFCs and clearly drinking water is not the sole or even primary source of exposure in the general population. Much remains to be learned about other sources of exposure, and the specific contribution of drinking water in this community. Levels of these chemicals in the United States general population have been declining in recent years, presumably due to reduced exposures following the decision by 3M to cease manufacture of PFOS[3]. Given the actions taken

to reduce PFCs in the drinking water, and the gradual elimination of PFCs from body tissues, PFC serum levels are likely to decline in these East Metro communities to levels comparable to those found in the general population.

No risk assessment-based or clinic-based values are currently established for interpreting PFC levels in serum in terms of public health risks. However, research is underway to develop human biomonitoring values or biomonitoring equivalents which may be helpful for informing future biomonitoring efforts and recommendations.

RECOMMENDATIONS

The preliminary data analysis for the East Metro PFC Biomonitoring Pilot Project was presented to the EHTB Advisory Panel on June 2, 2009. After reviewing these analyses the panel recommended that follow up sampling occur at some point in the future to verify that PFC serum concentrations are declining as expected based on actions taken to reduce exposure in the drinking water.

Further analysis of the project sample and available water exposure data has also been recommended by the Advisory Panel to examine the contribution of prior unfiltered drinking water levels, measured in 2005-2007, to the serum PFC concentrations measured in this study, and this will be completed at a later date. To resolve questions about the other sources of exposure, a more complete exposure assessment survey would be needed.

The Minnesota Legislature directed MDH to conduct the pilot biomonitoring projects in a manner that is community-based, thus involving community members to the extent possible in providing input in to the project, including the development of recommendations. As these project findings are presented to the community, additional recommendations will be solicited from the community for follow-up or any further investigation of PFC exposure.

As stated previously, one purpose of this project was to inform recommendations for a future biomonitoring program for the state of Minnesota. The project succeeded in this respect and the

information and experience it provided are necessary and valuable to the success of future projects.

For future biomonitoring projects directed at the communities residing in East Metro and similar urban communities, several recommendations can be made:

- Provide a significant lead time into the project to engage community partners and members; approximately one year is needed prior to project recruitment to identify the most effective means of ensuring wide project participation and acceptance by community members.
- Consider methods for including children and teens in future biomonitoring projects that involve a blood draw and potential risk to the participant that will also provide a health benefit to the child thus addressing ethical concerns and community priorities.
- Depending on the size of the population being sampled, one to three additional staff members are recommended to work with the community/participants during the recruitment and specimen collection phase of the project protocol
- Flexible hours and more time are needed to better accommodate participant's schedules for blood sample collection; this could include a project phlebotomist to accommodate people working non-traditional schedules.
- Conduct a feasibility study to determine the number of likely eligible participants in order to better anticipate the number of household contacts, and resources needed to achieve the desired study sample size; a larger sample size would increase analytical capacity for examining differences between population subgroups. A feasibility study should also consider inclusion of a Minnesota comparison group without drinking water contamination.

REFERENCES

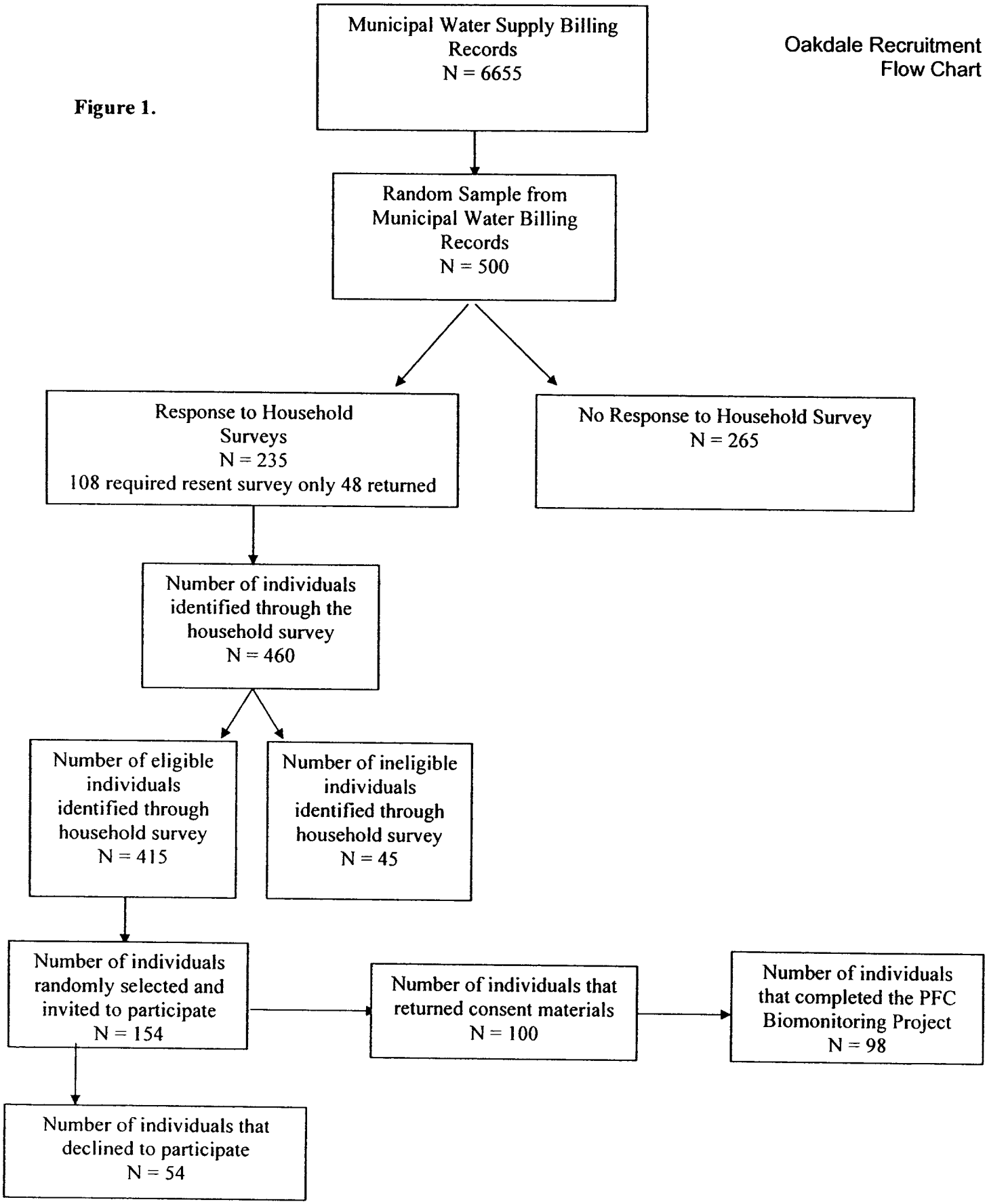
1. Yingling JKaV. Perfluorochemical Contamination in Lake Elmo and Oakdale, Washington County, Minnesota: a Public Health Assessment. 2008.
2. Calafat AM, Wong LY, Kuklenyik Z, Reidy JA, Needham LL. Polyfluoroalkyl chemicals in the U.S. population: data from the National Health and Nutrition Examination Survey (NHANES) 2003-2004 and comparisons with NHANES 1999-2000. *Environ Health Perspect.* Nov 2007;115(11):1596-1602.
3. Olsen GW, Mair DC, Church TR, et al. Decline in perfluorooctanesulfonate and other polyfluoroalkyl chemicals in American Red Cross adult blood donors, 2000-2006. *Environ Sci Technol.* Jul 1 2008;42(13):4989-4995.
4. Kuklenyik Z, Reich JA, Tully JS, Needham LL, Calafat AM. Automated solid-phase extraction and measurement of perfluorinated organic acids and amides in human serum and milk. *Environ Sci Technol.* Jul 1 2004;38(13):3698-3704.
5. Lubin JH, Colt JS, Camann D, et al. Epidemiologic evaluation of measurement data in the presence of detection limits. *Environ Health Perspect.* Dec 2004;112(17):1691-1696.
6. Emmett EA, Shofer FS, Zhang H, Freeman D, Desai C, Shaw LM. Community exposure to perfluorooctanoate: relationships between serum concentrations and exposure sources. *J Occup Environ Med.* Aug 2006;48(8):759-770.
7. Calafat AM, Kuklenyik Z, Caudill SP, Reidy JA, Needham LL. Perfluorochemicals in pooled serum samples from United States residents in 2001 and 2002. *Environ Sci Technol.* Apr 1 2006;40(7):2128-2134.
8. Calafat AM, Kuklenyik Z, Reidy JA, Caudill SP, Tully JS, Needham LL. Serum concentrations of 11 polyfluoroalkyl compounds in the u.s. population: data from the national health and nutrition examination survey (NHANES). *Environ Sci Technol.* Apr 1 2007;41(7):2237-2242.
9. Steenland K JC, MacNeil J, Lally C, Ducatman A, Vieira V, and Fletcher T. Predictors of PFOA Levels in a Community Surrounding a Chemical Plant. *Environ Health Perspect.* Vol In Press. In Press ed; 2009.
10. Holzer J, Midasch O, Rauchfuss K, et al. Biomonitoring of perfluorinated compounds in children and adults exposed to perfluorooctanoate-contaminated drinking water. *Environ Health Perspect.* May 2008;116(5):651-657.
11. Olsen GW, Burris JM, Burlew MM, Mandel JH. Epidemiologic assessment of worker serum perfluorooctanesulfonate (PFOS) and perfluorooctanoate (PFOA) concentrations and medical surveillance examinations. *J Occup Environ Med.* Mar 2003;45(3):260-270.
12. Steenland K FT, Savitz D. Status Report: Factors Associated with PFOA Levels in a community surrounding a chemical plant; 2008.
13. Wilhelm M, Angerer J, Fromme H, Holzer J. Contribution to the evaluation of reference values for PFOA and PFOS in plasma of children and adults from Germany. *Int J Hyg Environ Health.* Dec 24 2007.
14. Sakr CJ, Kreckmann KH, Green JW, Gillies PJ, Reynolds JL, Leonard RC. Cross-sectional study of lipids and liver enzymes related to a serum biomarker of exposure (ammonium perfluorooctanoate or APFO) as part of a general health survey in a cohort of occupationally exposed workers. *J Occup Environ Med.* Oct 2007;49(10):1086-1096.

15. Olsen GW, Burris JM, Ehresman DJ, et al. Half-life of serum elimination of perfluorooctanesulfonate,perfluorohexanesulfonate, and perfluorooctanoate in retired fluorochemical production workers. *Environ Health Perspect.* Sep 2007;115(9):1298-1305.
16. Olsen GW, Buehrer, B.D., Cox, R.L., Nunnally, M.C., and Ramm, K. H. *Descriptive Analysis of Perfluorobutyrate (PFBA) and Perfluorobutanesulfonate (PFBS) in Sera Collected in 2006 from 3M Cordova Electronic Materials Factory Employees.* St. Paul: 3M; July 30, 2007 2007. Epidemiology, 220-6W-08.
17. Chang SC, Das K, Ehresman DJ, et al. Comparative pharmacokinetics of perfluorobutyrate in rats, mice, monkeys, and humans and relevance to human exposure via drinking water. *Toxicol Sci.* Jul 2008;104(1):40-53.
18. Olsen GW, Chang SC, Noker PE, et al. A comparison of the pharmacokinetics of perfluorobutanesulfonate (PFBS) in rats, monkeys, and humans. *Toxicology.* Feb 4 2009;256(1-2):65-74.

FIGURES

Figure 1.

Oakdale Recruitment Flow Chart



Lake Elmo/Cottage Grove
Recruitment
Flow Chart

Figure 2.

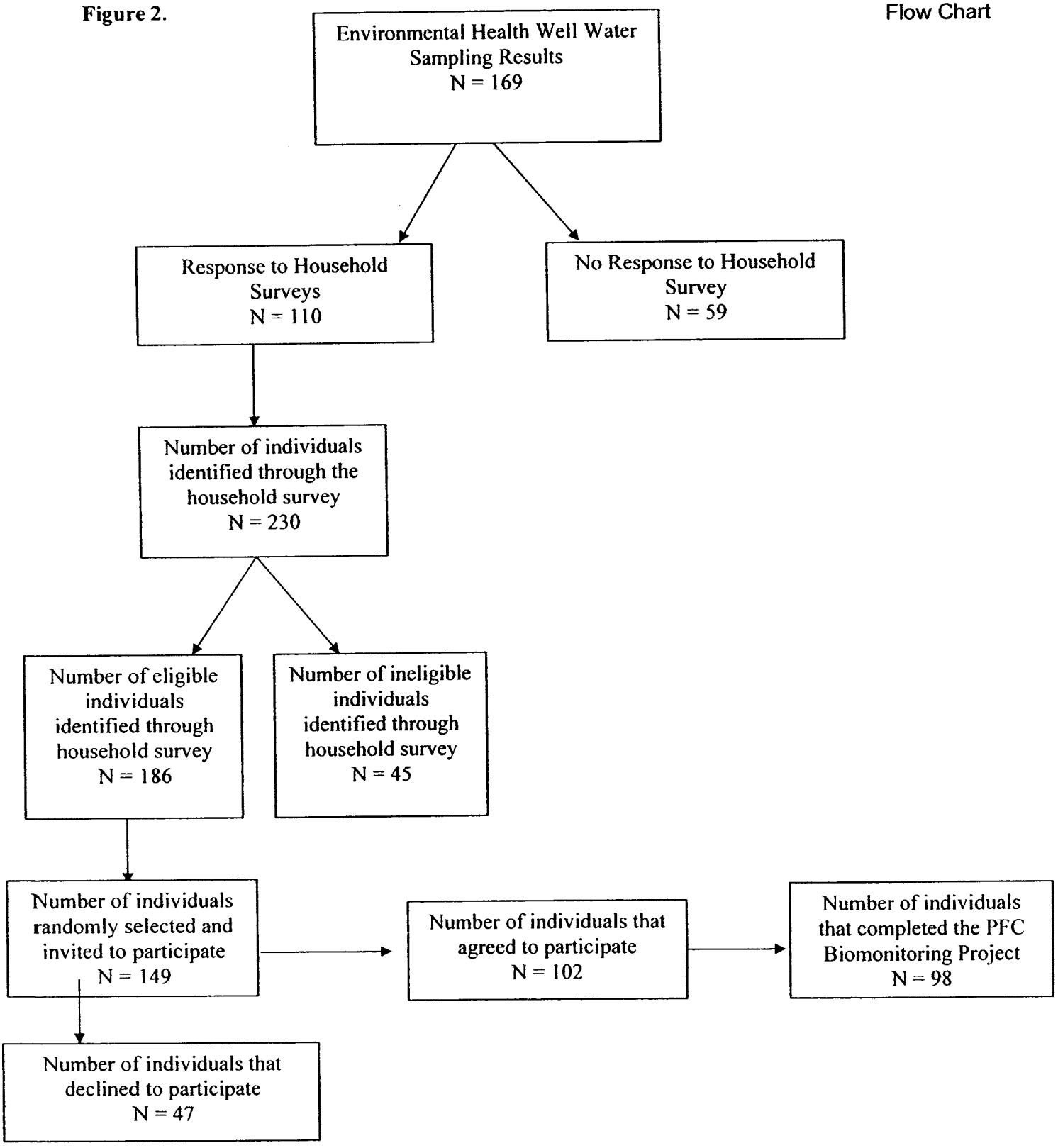


Figure 3. PFOA distribution for all 196 participants

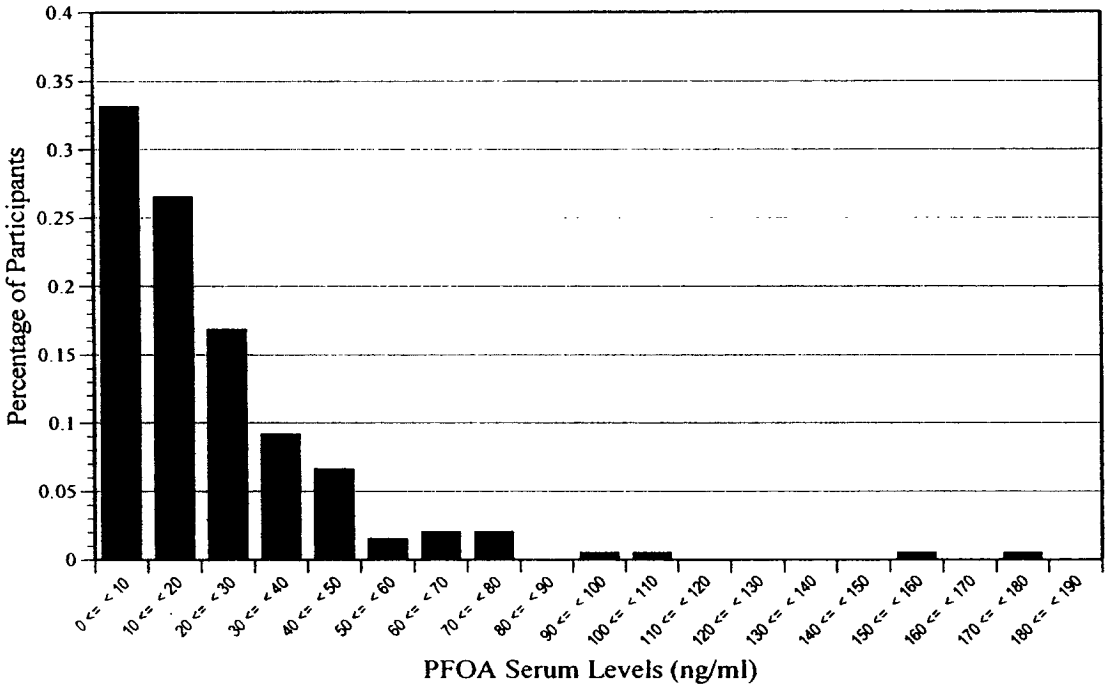


Figure 4. PFOA distribution for 98 participants in Private Well Water community

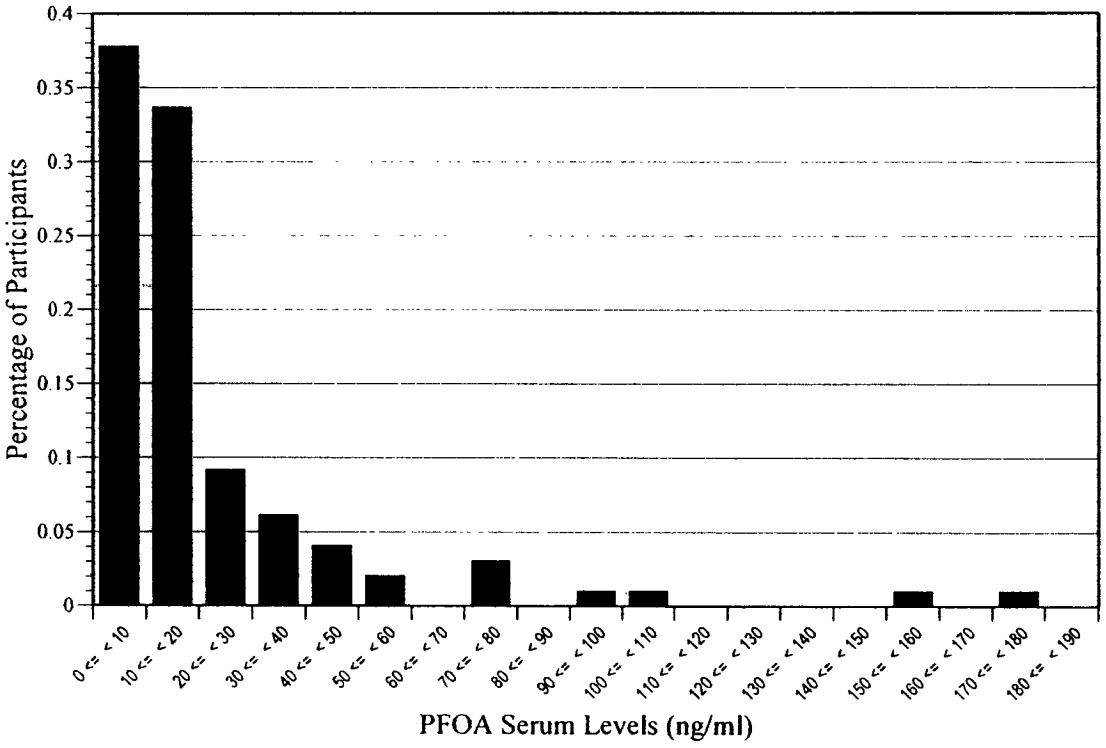


Figure 5. PFOA distribution for 98 participants from Municipal Water Supply

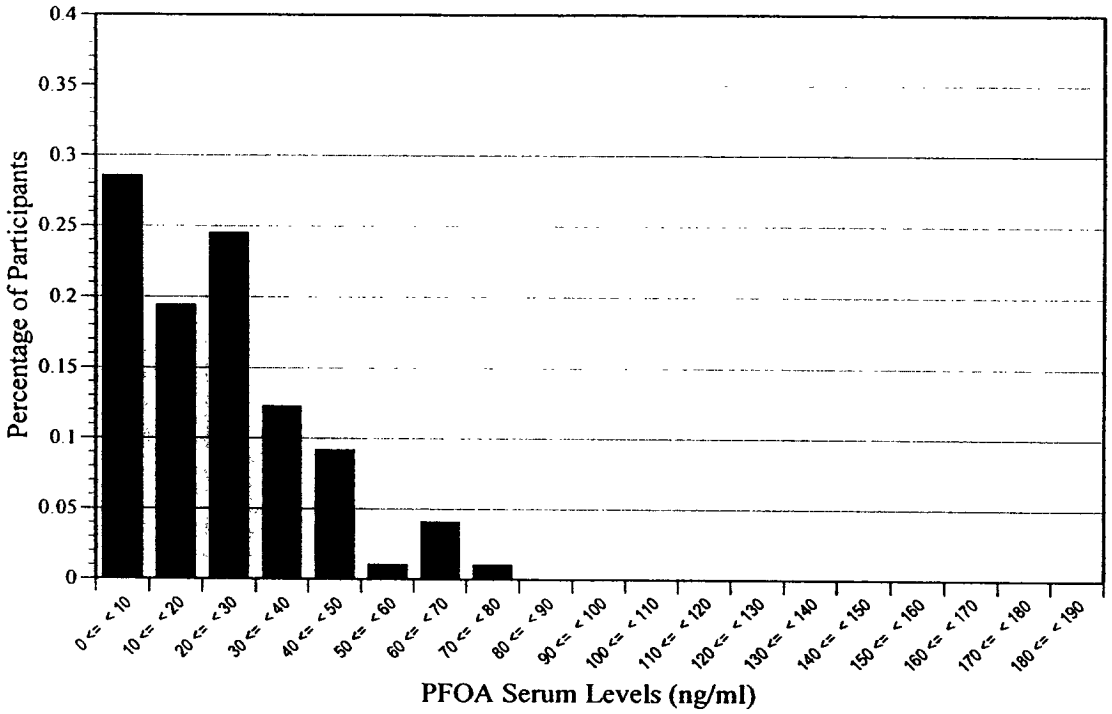


Figure 6. PFOS distribution for all 196 participants

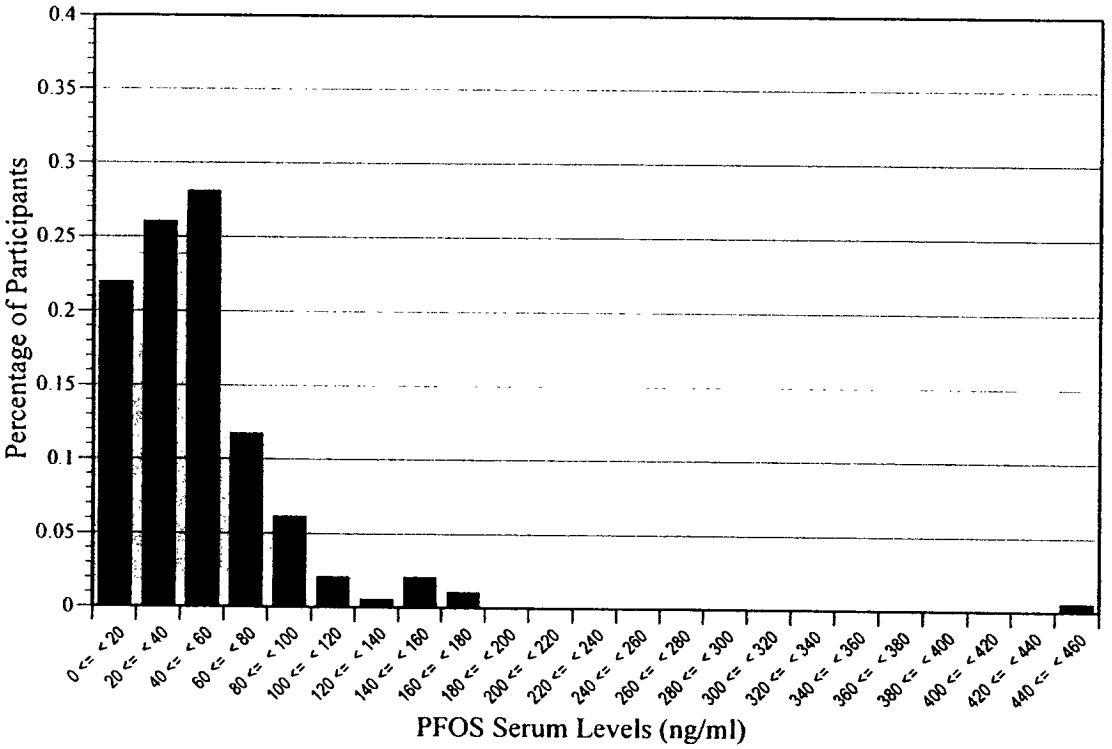


Figure 9. PFHxS distribution for all 196 participants

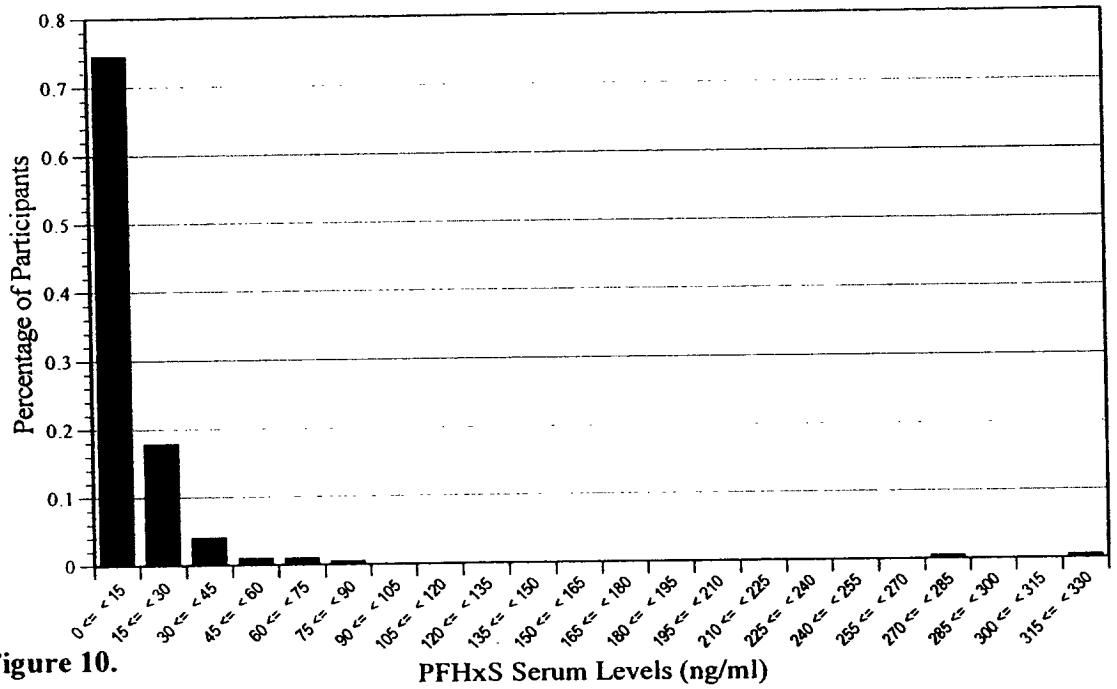


Figure 10. **PFHxS distribution for 98 participants in Private Well Water community**

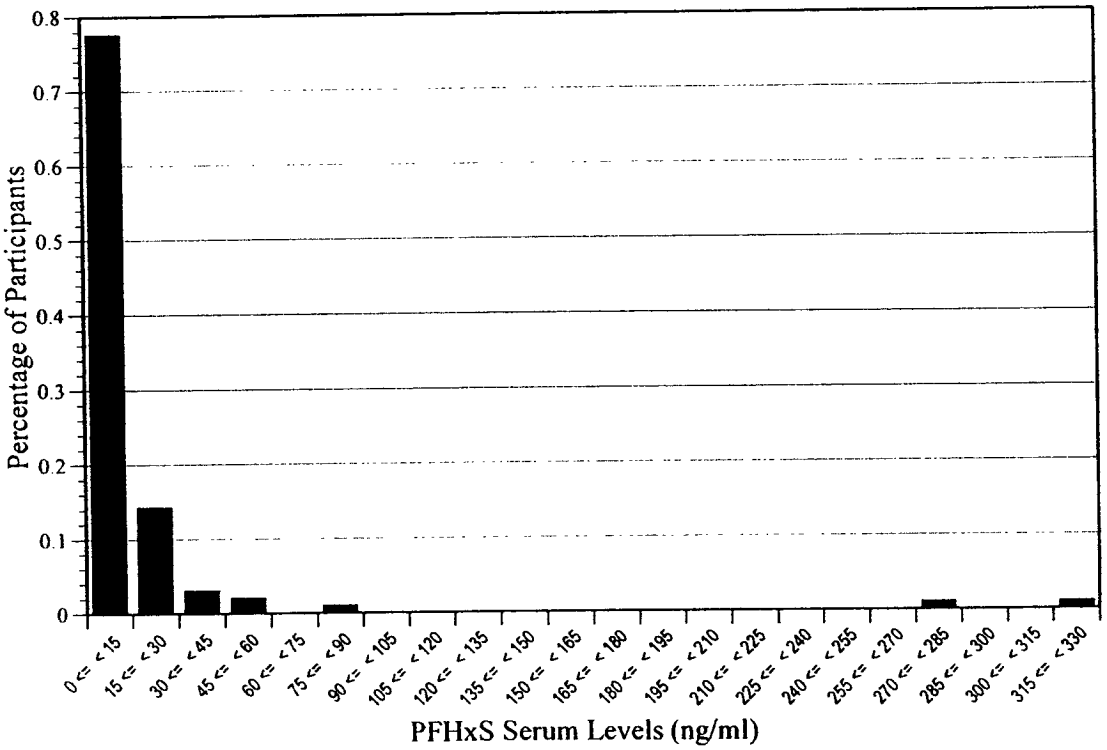


Figure 15. Scatterplot of Serum PFOA Concentration vs. Age

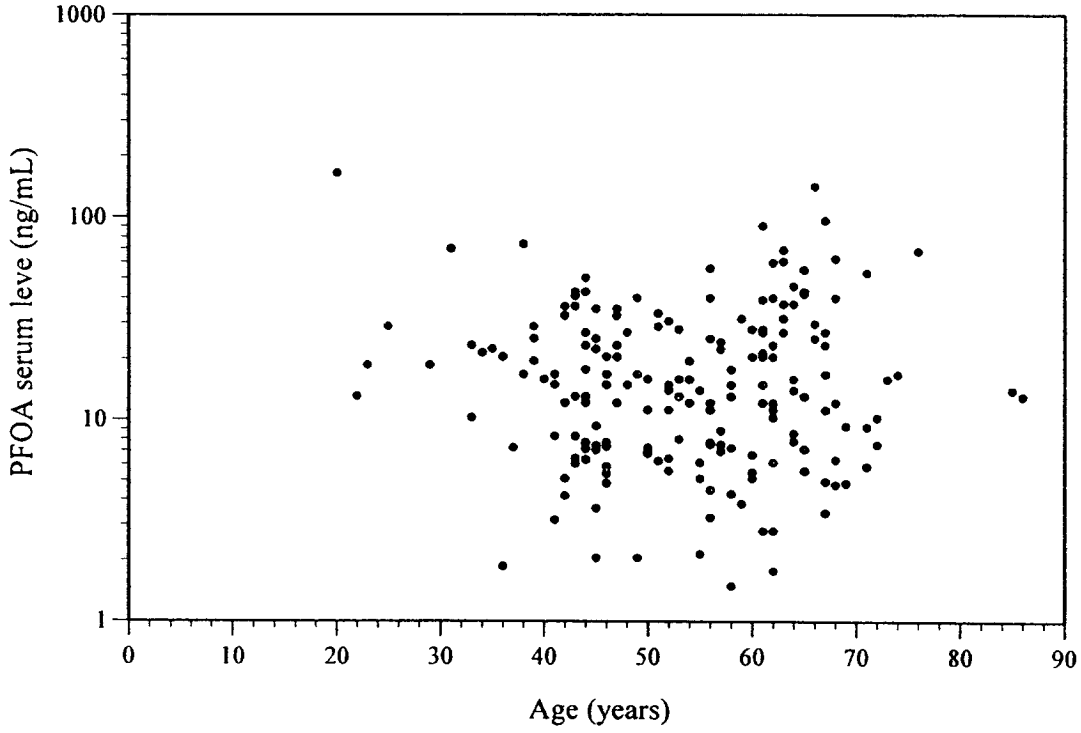


Figure 16. Scatterplot of Serum PFOS Concentration vs. Age

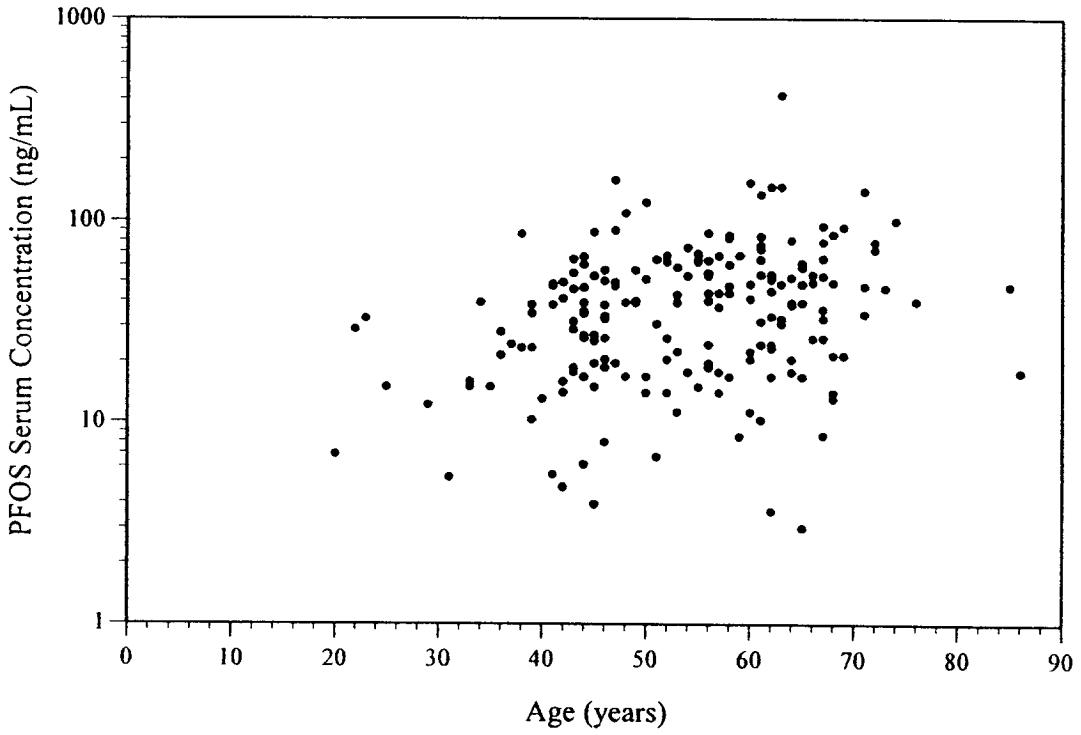


Figure 17. Scatterplot of Serum PFHxS Concentration vs. Age

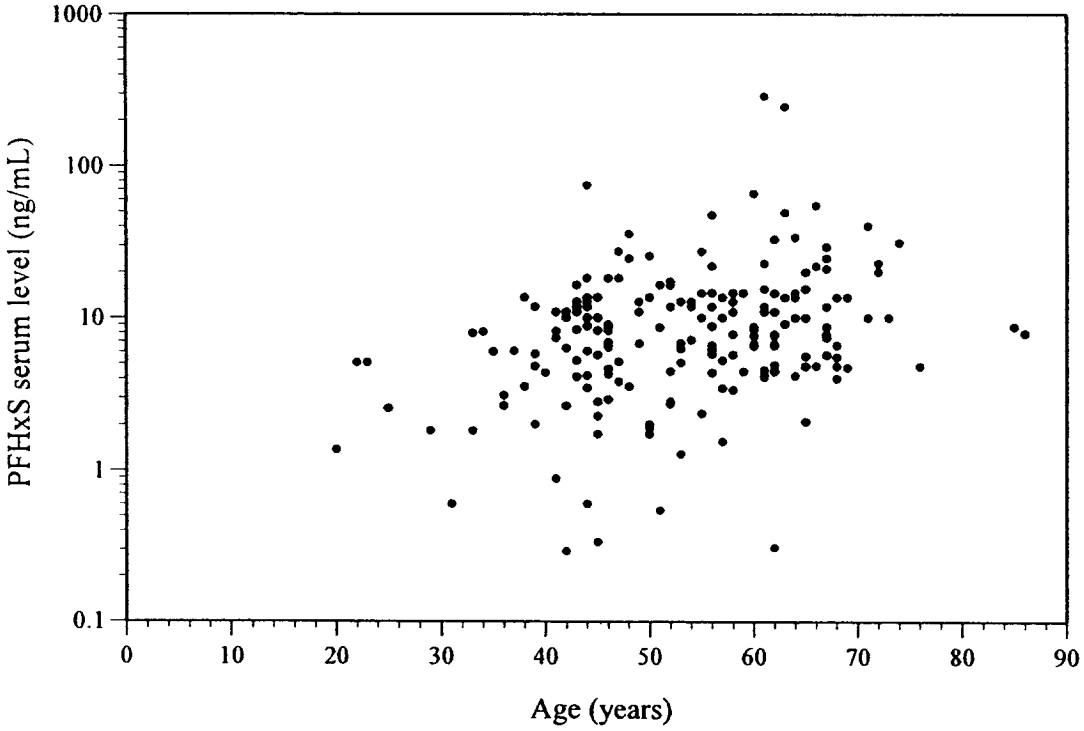


Figure 18. PFOA Serum Concentration by Age Category

Geometric mean with 95% confidence interval for each Age Category.

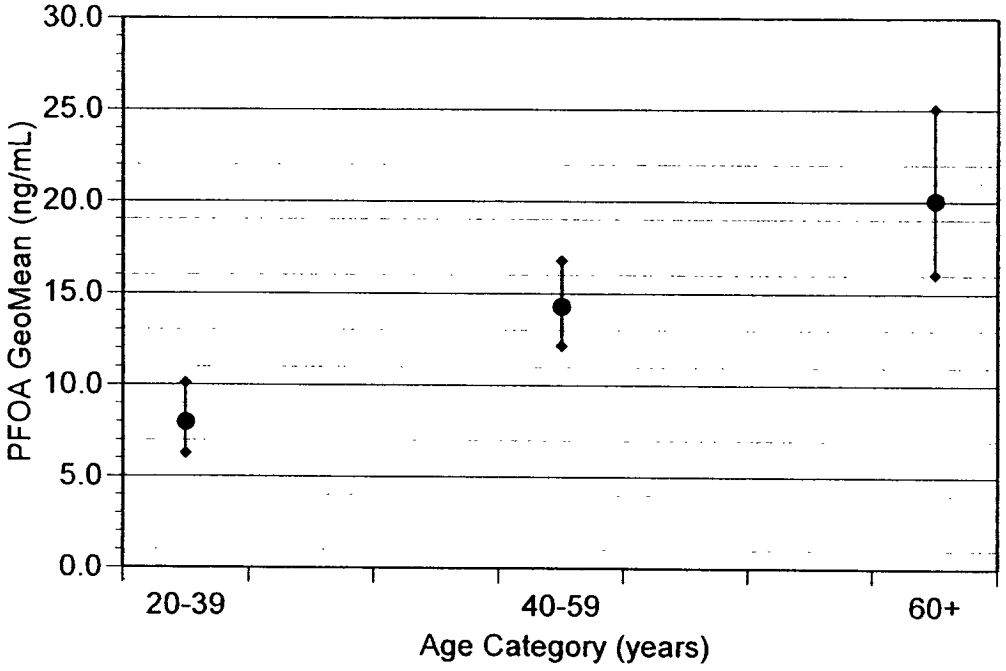


Figure 19. PFOS Serum Concentration by Age Category

Geometric mean with 95% confidence interval for each Age Category.

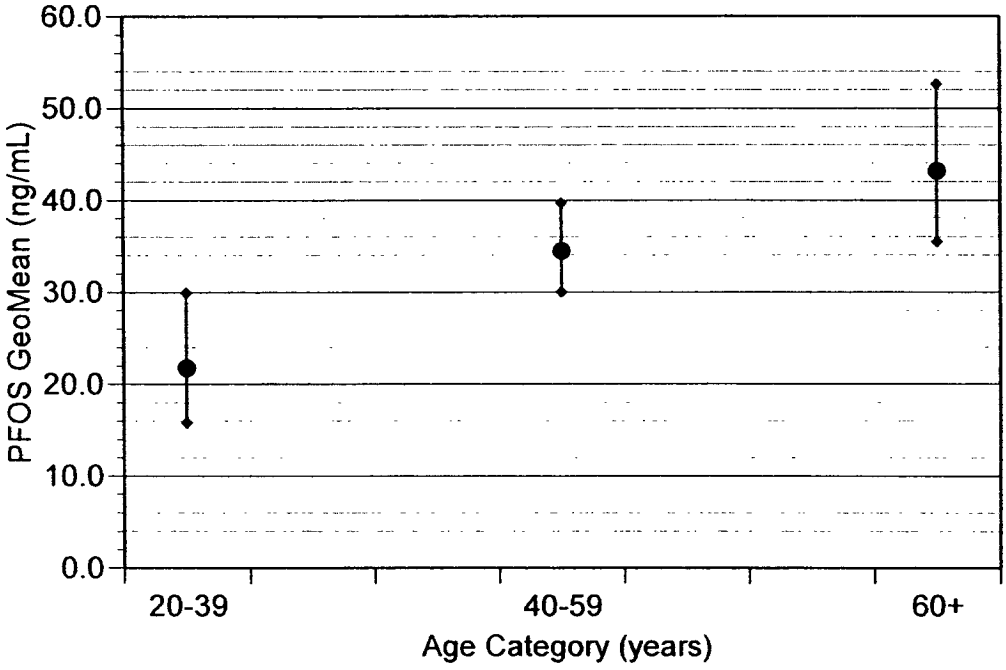


Figure 20. PFHxS Serum Concentration by Age Category

Geometric mean with 95% confidence interval for each Age Category.

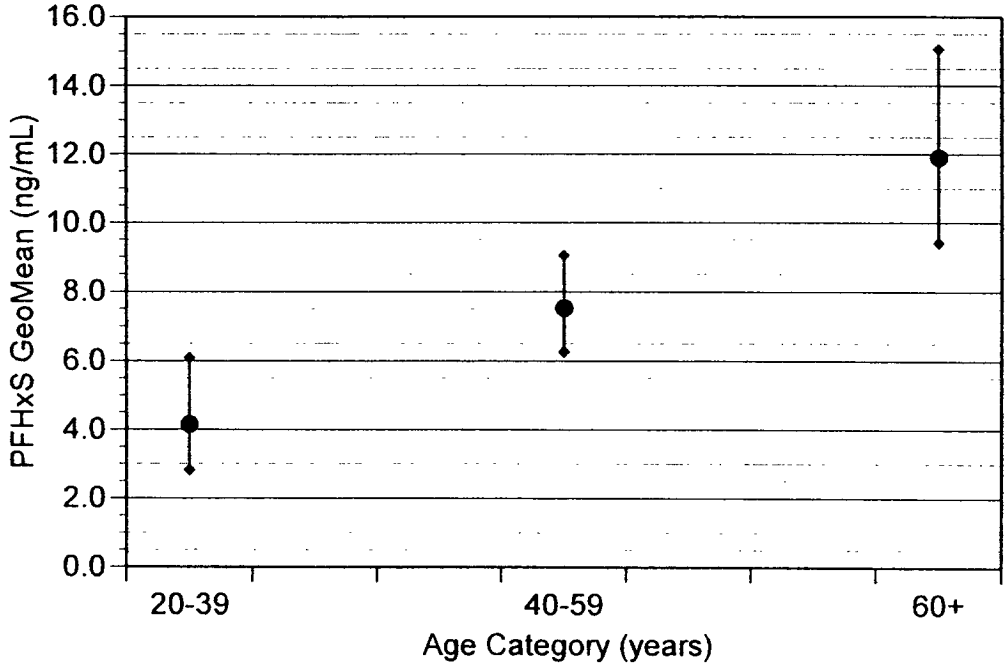


Figure 21. Scatterplot of Serum PFOA Concentration vs. Length of Residence

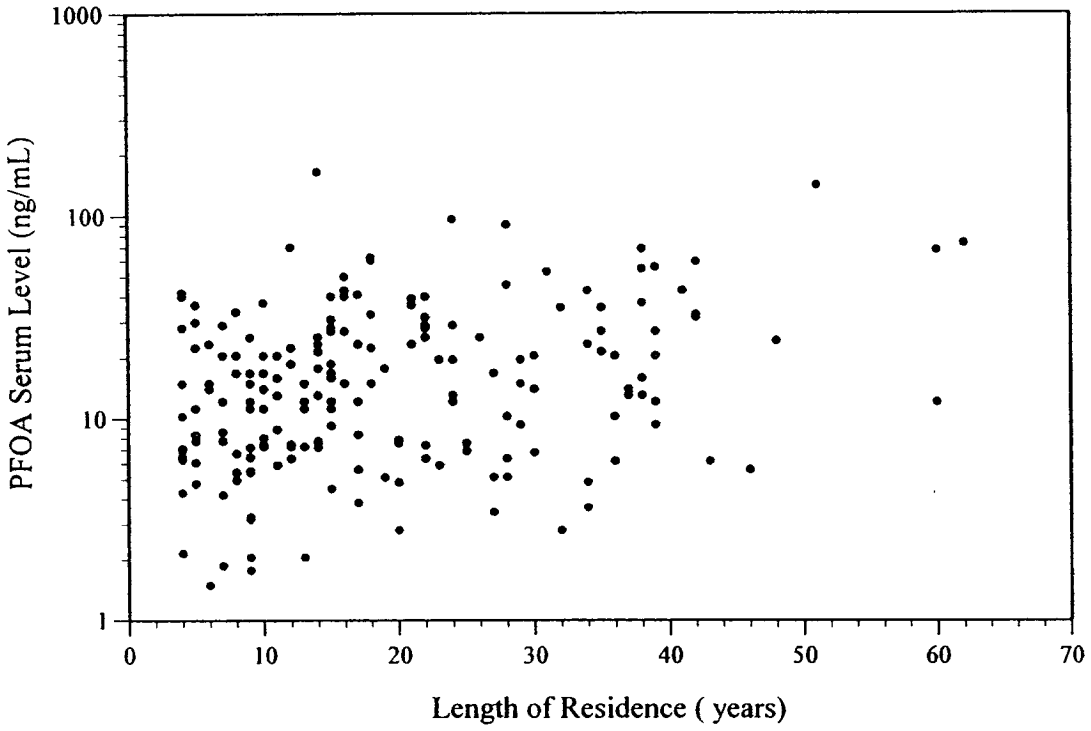


Figure 22. Scatterplot of Serum PFOS Concentration vs. Length of Residence

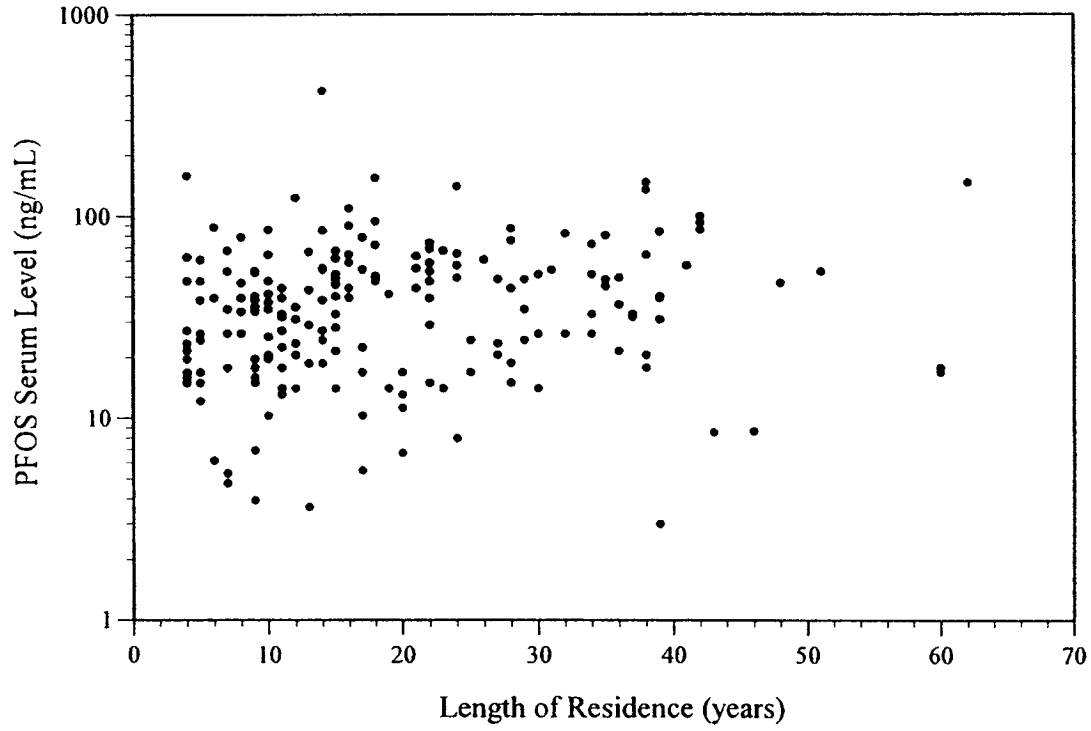


Figure 23. Scatterplot of Serum PFHxS Serum Concentration vs. Length of Residence

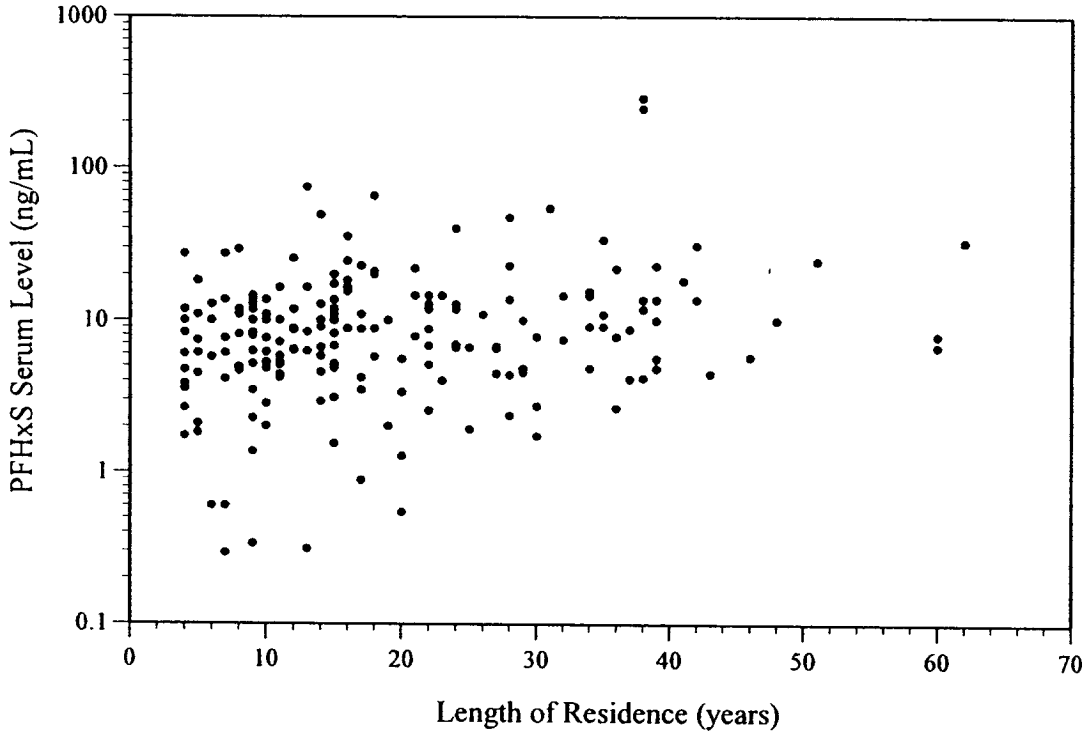


Figure 24. PFOA Serum Concentration by Length of Residence Category

Geometric mean with 95% confidence interval for each Length of Residence Category.

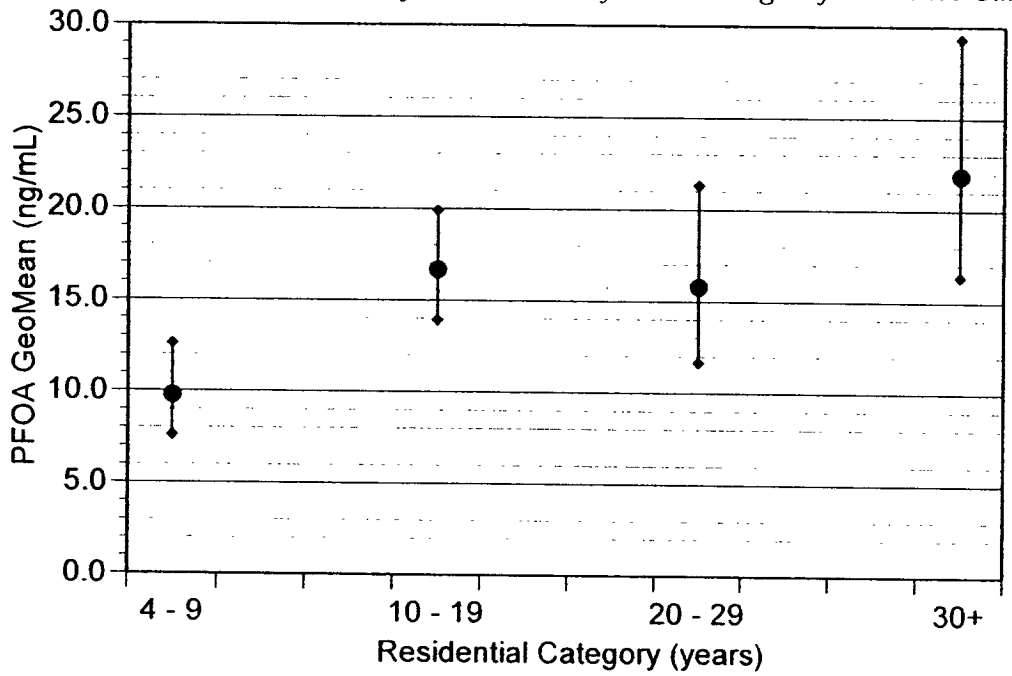


Figure 25. PFOS Serum Concentration by Length of Residence Category

Geometric mean with 95% confidence interval for each Length of Residence Category.

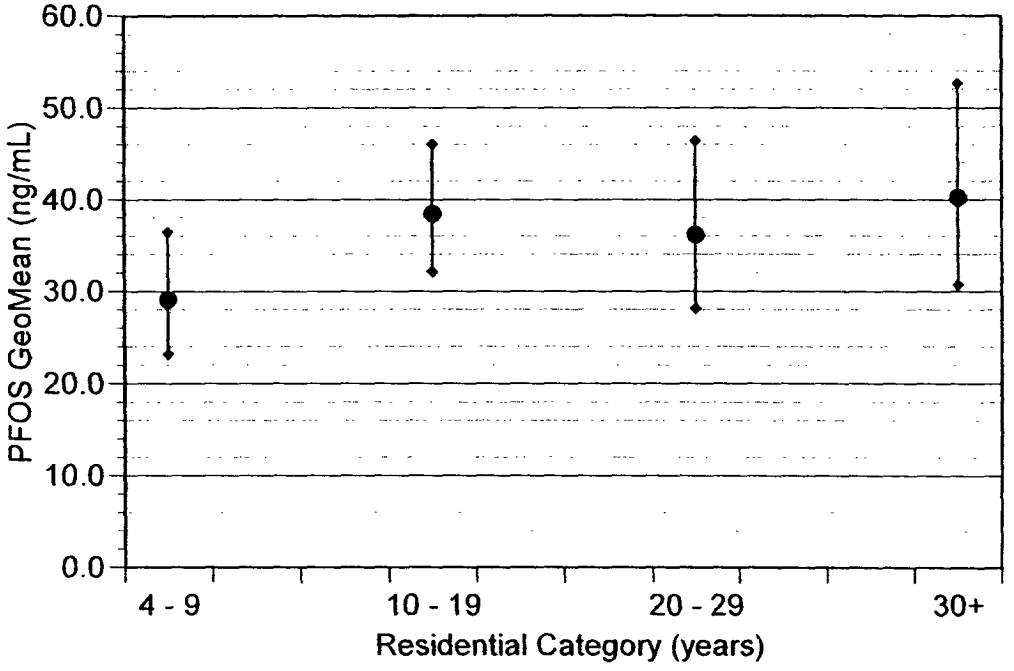
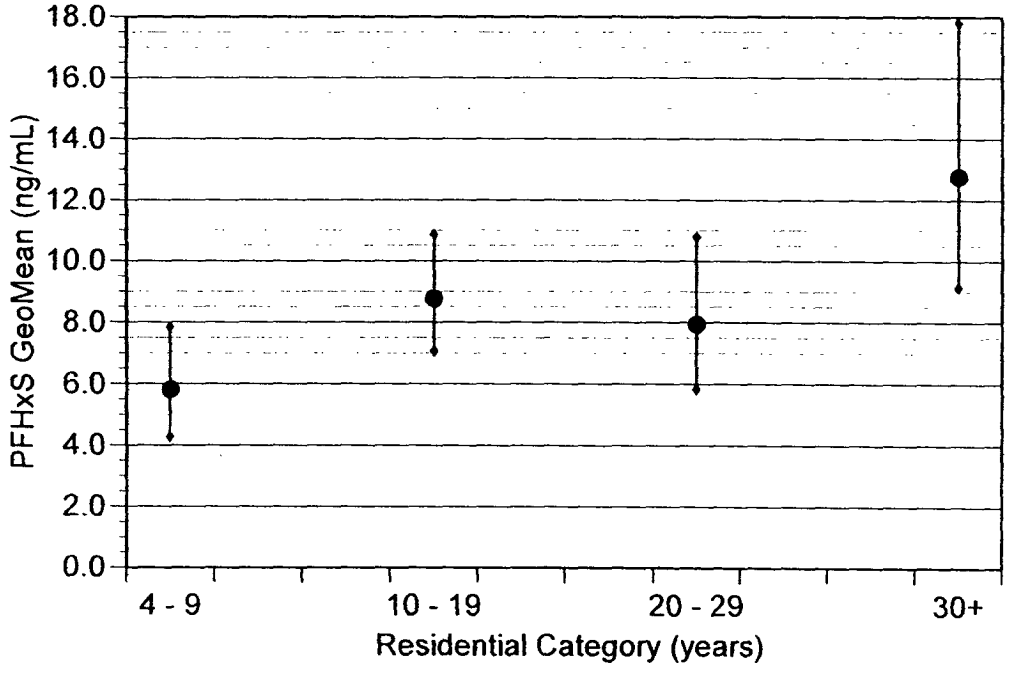


Figure 26. PFHxS Serum Concentration by Length of Residence Category

Geometric mean with 95% confidence interval for each Length of Residence Category.



TABLES

Table 1. Demographic Characteristics from the Household Survey
The survey requested that households provide information on each adult over the age of 20, who were residents prior to Jan. 1, 2005, and who currently lived in the home.

Oakdale	N = 415	Mean	Min	Max	Skew
Age	414	53.3	20	87	Normal
Residence Time in House	414	18.03	4	86	Log-Normal
Length of Time lived in Oakdale	390	20.46	3	85	Log-Normal
Male	196				
Female	215				
Lake Elmo/Cottage Grove	**N = 186**				
Age	186	51.11	20	86	Normal
Residence Time in House	181	18.13	4	60	Log-Normal
Male	88				
Female	89				

Table 2. Water Filtration/Treatment practices described on the Household Survey
Each household was asked to describe CURRENT water filtration or treatment practices used by the entire household.

Current Filtration/Treatment in Eligible Households	Oakdale N= 225(%)	Lake Elmo/Cottage Grove N = 95(%)
Multiple types used	32 (14)	24 (25)
Drinking water filtration/treatment responses		
Bottled Water Only	40(18)	8(8)
Reverse Osmosis System	17(8)	16(17)
Granulated Activated Carbon Filter (whole House)	3(1)	20(21)
None – no filtration Device	106(47)	33(35)

Table 3. Analytes and Internal Standards

Analyte	Acronym	Formula	CAS Number	Molecular weight	Report Level (ng/mL)
Perfluorobutanoic acid	PFBA	$C_4F_7O_2H$	375-22-4	214.04	0.1
Perfluoropentanoic acid	PFPeA	$C_5F_9O_2H$	2706-90-3	264.05	0.1
Perfluorohexanoic acid	PFHxA	$C_6F_{11}O_2H$	307-24-4	314.05	0.1
Perfluorooctanoic acid	PFOA	$C_8F_{15}O_2H$	335-67-1	414.07	0.1
Perfluorobutane sulfonate	PFBS	$C_4F_9SO_3H$	29420-49-3	299.09	0.1
Perfluorohexane sulfonate	PFHxS	$C_6F_{13}SO_3H$	432-50-7	399.11	0.1
Perfluorooctane sulfonate	PFOS	$C_8F_{17}SO_3H$	1763-23-1	499.12	0.1
Perfluoro-n-[1,2,3,4-$^{13}C_4$]butanoic acid	MPBFA	$^{13}C_4F_7O_2H$			
Perfluoro-n-[1,2-$^{13}C_2$]hexanoic acid	MPFHxA	$^{13}C_2{}^{12}C_4F_{11}O_2H$			
Perfluoro-n-[1,2,3,4,5-$^{13}C_5$]octanoic acid	MPFOA	$^{13}C_5{}^{12}C_3F_{15}O_2H$			
Perfluoro-1-hexane[$^{18}O_2$]sulfonate	MPFHxS	$C_6F_{13}S^{18}O_2{}^{16}OH$			
Perfluoro-1-[1,2,3,4-$^{13}C_4$]octane sulfonate	MPFOS	$^{13}C_4{}^{12}C_4SO_3H$			

Table 4. Accuracy and Precision

	1 ng/mL Spike Level		10 ng/mL Spike Level	
Analyte	**% Recovery**	**%RSD**	**% Recovery**	**%RSD**
PFBA	105.9	1.9	102.1	3.7
PFPeA	104.2	7.6	108.7	6.6
PFHxA	105.6	5.3	106.5	2.2
PFOA	100.3	7.1	101.7	1.7
PFBS	115.3	6.2	108.7	2.6
PFHxS	106.4	3.9	103.0	1.6
PFOS	110.9	5.9	98.7	1.5

Table 5. Method Detection Limit

Analyte	Spiking level ng/mL	MDL (ng/mL)	Report Level (ng/mL)
PFBA	0.1	0.024	0.1
PFPeA	0.1	0.037	0.1
PFHxA	0.1	0.038	0.1
PFOA	0.1	0.029	0.1
PFBS	0.1	0.024	0.1
PFHxS	0.1	0.013	0.1
PFOS	0.1	0.040	0.1

Table 8. Demographic Characteristics of the 196 Biomonitoring Pilot Project Participants – collected from the Household Survey

Oakdale	N = 98	Mean	Min	Max	Skew
Age	98	53.07	25	85	Normal
Residence Time in House	98	17.83	4	62	Log-Normal
Length of Time lived in Oakdale	98	20.74	3.5	62	Log-Normal
Male	44				
Female	54				

Lake Elmo/Cottage Grove	N = 98				
Age	98	53.31	20	86	Normal
Residence Time in House	98	19.83	4	60	Log-Normal
Male	44				
Female	54				

Gender	N = 196	Average Age	Average Length of Residence
Male	88	53.8	19.4
Female	108	53.3	18.6

3M Employment			
Worker	30	59.1	21.3
Non Worker	166	52.5	18.6

Table 9. Demographic Characteristics of the 196 biomonitoring pilot project participants – from the follow up phone survey.

Questionnaire Variable	Responses:		N = 196
Employment	**Yes**	**No**	
Have you ever worked at 3M?	30	166	
Ever worked in PFC Research?	3	27	
Ever worked in PFC production?	2	28	

Water	Unfiltered Tap	Filtered Tap	Bottled	Other
What type of water do you typically drink?	86	66	43	1

Filtration/Treatment	None	Whole House Carbon	Bottled	Sink Carbon	Kitchen Faucet	RO	Pitcher Filter
What type of water filter/treatment is used?	67	23	17	6	14	17	14

Ethnicity	Non-H White	Non-H Black	Hispanic	Asian American	Native American	Other
How would you describe your ethnicity?	187	0	1	3	1	4

Health	Very Good	Good	Bad	Very Bad
How would you describe your health?	97	93	6	0

Table 10. Perflurooctanoate – PFOA

Study and Population (Sample size)	Bio Specimen	Time period	Geometric Mean ng/mL (ppb)	Arithmetic Mean ng/mL (ppb)	Median ng/mL (ppb)	Range ng/mL (ppb)
MDH E. Metro PFC Biomonitoring Pilot Project (N=196)	Serum	Oct 2008 – Jan 2009	15.4	22.5	16	1.6 – 177
Female (108)			14.4	21.7	15	1.6 - 152
Male (88)			16.6	23.4	17	3.0 - 177
Well Water Community (98)			13.6	21.9	13	1.6 - 177
Municipal Water Supply Community (98)			17.3	22.9	21	2 - 79
Little Hocking, WV (N = 4,465) PFOA Levels in a Community (0 to >70 years of age) Surrounding a Chemical Plant. C8 study[12]	Serum	2005 – 2006	197		224.1	NA
Ohio River Valley (N = 64,251) PFOA Levels in a Community Surrounding a Chemical Plant. C8 study[9]	Serum	2005 - 2006	NA	83	28	0.25 – 22,412
US NHANES (N = 2,094) PFOA was measured in 2,094 individuals (12 to > 60 years of age) from a random sample of the United States Population in sampling years 2003 - 2004[2]	Serum	2003 – 2004	3.9 (3.6 – 4.3) Female 3.5 Male 4.5	4.3 Female 3.87 Male 4.79	4.0 Female 3.6 Male 4.6	0.1 – 77.2 0.1 – 45.9 0.1 – 77.2
Red Cross Blood Donors (N = 600) 600 blood samples (20 - 69 years of age) from 6 Red Cross blood centers (including the Twin Cities) were analyzed for PFCs in 2006[3]	Plasma	2006	3.4 Female 3.0 Male 3.9	3.9 Female 3.5 Male 4.4	3.6 Female 3.1 Male 4.0	<1.0 – 28.1 < 1.0 – 11.9 0.8 – 28.1
Germany (N; males = 103, females = 153) A random sample of females (age 23 to 49) and males (age 18 – 69) from North Rhine – Westphalia Germany.[13]	Plasma	Oct – Nov 2006	Female 3.2 Male 6.4	Female 2.8 Males 5.8	NA	NA
Germany (N; Males = 101, females = 164) A random sample of individuals from Arnsberg, Germany, an area with known PFC water contamination.[10]	Plasma	Sept – Nov 2006	Female 23.4 Male 25.3	Female 26.7 Male 28.5	NA	Female 5.4 -99.7 Male 6.1 – 77.5
Occupational Group (N=215) 3M production workers from the Decatur plant voluntarily had PFC measurments completed during medical surveillance.[11]	Serum	2000	1130	1780	NA	40 - 12700
Occupational Group (N = 1024) A group of Dupont workers volunteered to participate in a study investigating levels of PFOA and lipid levels.[14]	Serum	2004	NA	428	189	5 – 9550

Table 11. Perfluorooctansulfonate – PFOS

Study and Population (Sample size)	Bio Specimen	Time period	Geometric Mean ng/mL (ppb)	Arithmetic Mean ng/mL (ppb)	Median ng/mL (ppb)	Range ng/mL (ppb)
MDH E. Metro PFC Biomonitoring Pilot Project (N=196)	Serum	Oct 2008 – Jan 2009	35.9	47.7	41	3.2 - 448
Female (108)			30.5	40.6	35	3.2 - 151
Male (88)			43.9	56.4	45.5	9.1 - 448
Well Water Community (98)			32.9	47.4	35	3.2 - 448
Municipal Water Supply Community (98)			39.3	48	43	3.9 - 166
US NHANES (N = 2,094)	Serum	2003 - 2004	20.7	23.9	29.9	0.3 – 435
PFOS was measured in 2,094 individuals (12 to > 60 years of age) from a random sample of the United States Population in sampling years 2003 - 2004[2]			Female 18.4	Female 21.6	Female 18.2	Female .3 – 406
			Male 23.3	Male 26.1	Male 23.9	Male .3 - 435
Red Cross Blood Donors (N = 600)	Plasma	2006	14.5	16.9	14.2	<2.5 – 77.9
600 blood samples (20 - 69 years of age) from 6 Red Cross centers (including the Twin Cities) were analyzed for PFCs in 2006[3]			Female 12.3	Female 14.5	Female 11.9	Female < 2.5 – 77.9
			Male 17.1	Male 19.3	Male 16.8	Male <2.5 – 62.4
Germany (N; males = 204, females = 317)	Plasma	Oct – Nov 2006	Female 5.5	Female 6.3	Female 5.4	NA
A random sample of females (age 23 to 49) and males (age 18 – 69) from North Rhine – Westphalia Germany.[13]			Male 10.1	Male 12.1	Male 10.5	
Germany (N; Males = 101, females = 164)	Plasma	Sept – Nov 2006	Female 5.8	Female 6.3	NA	Females 1.7 – 16.7
A random sample of individuals from Arnsberg, Germany, an area with known PFC water contamination.[10]			Male 10.5	Male 11.8		Males 2.7 – 36.2
Occupational Group (N=215)	Serum	2000				
3M production workers from the Decatur plant voluntarily had PFC measurements completed during medical surveillance.[11]			440	800	NA	10 - 7040

Table 12. Perfluorhexanesulfonate – PFHxS

Study and Population (Sample size)	Bio Specimen	Time period	Geometric Mean ng/mL (ppb)	Arithmetic Mean ng/mL (ppb)	Median ng/mL (ppb)	Range ng/mL (ppb)
MDH E. Metro PFC Biomonitoring Pilot Project (N=196)	Serum	Oct 2008 – Jan 2009	8.4	14.8	8.9	0.32 – 316
Female (108)			7.0	13.1	7.4	0.32 – 316
Male (88)			10.6	16.8	10.5	1.7 - 270
Well Water Community (98)			8.3	17.1	7.5	0.37 - 316
Municipal Water Supply Community (98)			8.6	12.4	9.8	0.32 - 72
US NHANES (N = 2,094)	Serum	2003 - 2004	1.9	2.9	1.9	0.2 - 82
PFHxS was measured in 2,094 individuals (12 to > 60 years of age) from a random sample of the United States Population in sampling years 2003 - 2004[2]			Female 1.7	Female 2.8	Female 2.9	Female 0.2 – 64.1
			Male 2.2	Male 3.1	Male 3.3	Male 0.2 - 82
Red Cross Blood Donors (N = 600)	Plasma	2006	1.5	2.2	1.5	<0.5 – 28.1
600 blood samples (20 -69 years of age) from 6 Red Cross centers (including the Twin Cities)were analyzed for PFCs in 2006[3]			Female 1.2	Female 1.6	Female 1.2	Female 0.7 – 1.8
			Male 1.9	Male 2.9	Male 1.8	Male 1.2 – 2.8
Germany (N; Males = 101, females = 164)	Plasma	Sept – Nov 2006	Female 1.1	Female 1.2	NA	Females <0.1 – 1.1
A random sample of individuals from Arnsberg, Germany, an area with known PFC water contamination.[10]			Male 2.5	Male 2.7		Males 0.7 – 2.5
Occupational Group (N=26)	Serum	2002 - 2004	NA	182	117	10 - 791
3M production workers, 3 from the 3M Cottage Grove chemical division, voluntarily had PFC measurments completed to determine the half life of certain PFCs.[15]						

Table 13. Pefluorbutyrate – PFBA

Study and Population (sample size)	Bio Specimen	Time Period	50th percentile	75th percentile	95th percentile	99th percentile	Minimum Value	Maximum Value
MDH E. Metro PFC Biomonitoring Pilot Project (N=196)	Serum	Oct 2008 – Jan 2009	< LOD*	.135	.68	5.6	< LOD*	8.5
Female (108)			<LOD*	.14	.68	5.6	<LOD*	8.5
Male (88)			<LOD*	.12	.42	.53	<LOD*	1.1
Well Water Community (98)			<LOD*	.11	1.0	5.6	<LOD*	5.6
Municipal Water Supply Community (98)			<LOD*	.15	.52	8.5	<LOD*	8.5
Occupational Group (N = 28) PFBA and PFBS were measured in employees of the Cordova electronic materials factory.[16]	Serum	2006	8.0	NA	NA	NA	<0.5	56.7
Occupational Group (N = 177) PFBA was measured in 177 former (127) and current (50) 3M employees from Washington and Dakota Counties.[17]	Serum	Fall 2005 – Spring 2006	<LLOQ**	.5 - <1.0	2.0 - < 3.0	5.0 - < 6.0	<LLOQ**	6.2

* LOD is Limit of detection = .10 ng/mL

**LLOQ is lower limit of quantification = .5 ng/mL

Table 14. Perfluorobutanesulfonate – PFBS

Study and Population (sample size)	Bio Specimen	Time Period	50th percentile	75th percentile	95th percentile	99th percentile	Minimum Value	Maximum Value
MDH E. Metro PFC Biomonitoring Pilot Project (N=196)	Serum	Oct 2008 – Jan 2009	<LOD*	<LOD*	<LOD*	.16	<LOD*	.18
			<LOD*	<LOD*	<LOD*	.15	<LOD*	.15
Female (108)			<LOD*	<LOD*	<LOD*	.18	<LOD*	.18
Male (88)								
Well Water Community (98)			<LOD*	<LOD*	<LOD*	.18	<LOD*	.18
Municipal Water Supply Community (98)			<LOD*	<LOD*	<LOD*	.15	<LOD*	.15
Occupational Group (N = 28)	Serum	2006	7.3	NA	NA	NA	0.5	128.0
PFBA and PFBS were measured in employees of the Cordova electronic materials factory.[16]								
Occupational Group (N = 6)	Serum	June 2004 – Dec 2004	363	NA	NA	NA	92	921
PFBS was measured in 6 3M employees to determine the half life of the chemical in the body.[18]								

* LOD is Limit of detection = .10 ng/mL

Table 15. Comparison Analyses by Gender

Variable	N	Statistic	P value	Means
Age	Females 108 Males 88	t test	0.76	Males 53.7 Females 53.3
Length of Residence	Females 108 Males 88	t test	0.67	Males 19.4 Females 18.6
Oakdale Years (Municipal water only)	Females 53 Males 41	t test	0.05	Males 23.6 Females 18.5
PFOA	Females 108 Males 88	t test	0.26	Males 16.6 Females 14.4
PFOS	Females 108 Males 88	t test	0.001	Males 43.9 Females 30.5
PFHxS	Females 108 Males 88	t test	0.004	Males 10.6 Females 7.0

Table 16. Comparison Analyses by Community (Municipal Water Supply vs. Private Well Water)

Variable	N	Statistic	P value	Means
Age	Municipal 98 Private Well 98	t test	0.7	Municipal 53.07 Private 53.31
Length of Residence	Municipal 98 Private well 97	t test	0.37	Municipal 17.83 Private 19.83
PFOA	Municipal 98 Private Well 98	t test	0.06	Municipal 17.3 Private 13.6
PFOS	Municipal 98 Private Well 98	t test	0.11	Municipal 39.3 Private 32.9
PFHxS	Municipal 98 Private Well 98	t test	0.78	Municipal 8.6 Private 8.3

Table 17. Comparison Analyses by Employment History (3M worker vs. non-worker)

Variable	N	Statistic	P value	Means
Age	Non Workers 166 Workers 30	t test	0.001	Workers 59.1 Non Workers 52.5
Length of Residence	Non Workers 166 Workers 30	t test	0.29	Workers 21.3 Non Workers 18.6
PFOA	Non Workers 166 Workers 30	t test	0.52	Workers 17.0 Non Workers 15.06
PFOS	Non Workers 166 Workers 30	t test	0.07	Workers 45.5 Non Workers 34.5
PFHxS	Non Workers 166 Workers 30	t test	0.003	Workers 12.4 Non Workers 7.9

Table 18. Correlations Between PFOA, PFOS, and PFHxS

Perflurochemicals Pearson Correlation[R]	PFOA	PFOS	PFHxS
PFOA	1		
PFOS	0.76 ($p < 0.0001$)	1	
PFHxS	0.76 ($p < 0.0001$)	0.81 ($p < 0.0001$)	1

APPENDICES

Appendix A

Minnesota Environmental Health Tracking And Biomonitoring 2007

$1,000,000 each year is for environmental health tracking and biomonitoring. Of this amount, $900,000 each year is for transfer to the Department of Health. The base appropriation for this program for fiscal year 2010 and later is $500,000.

144.995 DEFINITIONS; ENVIRONMENTAL HEALTH TRACKING AND BIOMONITORING.

(a) For purposes of sections 144.995 to 144.998, the terms in this section have the meanings given.

(b) "Advisory panel" means the Environmental Health Tracking and Biomonitoring Advisory Panel established under section 144.998.

(c) "Biomonitoring" means the process by which chemicals and their metabolites are identified and measured within a biospecimen.

(d) "Biospecimen" means a sample of human fluid, serum, or tissue that is reasonably available as a medium to measure the presence and concentration of chemicals or their metabolites in a human body.

(e) "Commissioner" means the commissioner of the Department of Health.

(f) "Community" means geographically or nongeographically based populations that may participate in the biomonitoring program. A "nongeographical community" includes, but is not limited to, populations that may share a common chemical exposure through similar occupations, populations experiencing a common health outcome that may be linked to chemical exposures, populations that may experience similar chemical exposures because of comparable consumption, lifestyle, product use, and subpopulations that share ethnicity, age, or gender.

(g) "Department" means the Department of Health.

(h) "Designated chemicals" means those chemicals that are known to, or strongly suspected of, adversely impacting human health or development, based upon scientific, peer-reviewed animal, human, or in vitro studies, and baseline human exposure data, and consists of chemical families or metabolites that are included in the federal Centers for Disease Control and Prevention studies that are known collectively as the National Reports on Human Exposure to Environmental Chemicals Program and any substances specified by the commissioner after receiving recommendations under section 144.998, subdivision 3, clause (6).

(i) "Environmental hazard" means a chemical or other substance for which scientific, peer-reviewed studies of humans, animals, or cells have demonstrated that the chemical is known or reasonably anticipated to adversely impact human health.

(j) "Environmental health tracking" means collection, integration, analysis, and dissemination of data on human exposures to chemicals in the environment and on diseases potentially caused or aggravated by those chemicals.

144.996 ENVIRONMENTAL HEALTH TRACKING; BIOMONITORING.

Subdivision 1. **Environmental health tracking.** In cooperation with the commissioner of the Pollution Control Agency, the commissioner shall establish an environmental health tracking program to:

(1) coordinate data collection with the Pollution Control Agency, Department of Agriculture, University of Minnesota, and any other relevant state agency and work to promote the sharing of and access to health and environmental databases to develop an environmental health tracking system for Minnesota, consistent with applicable data practices laws;

(2) facilitate the dissemination of aggregate public health tracking data to the public and researchers in accessible format;

(3) develop a strategic plan that includes a mission statement, the identification of core priorities for research and epidemiologic surveillance, and the identification of internal and external stakeholders, and a work plan describing future program development and addressing issues having to do with compatibility with the Centers for Disease Control and Prevention's National Environmental Public Health Tracking Program;

(4) develop written data sharing agreements as needed with the Pollution Control Agency, Department of Agriculture, and other relevant state agencies and organizations, and develop additional procedures as needed to protect individual privacy;

(5) organize, analyze, and interpret available data, in order to:

(i) characterize statewide and localized trends and geographic patterns of population-based measures of chronic diseases including, but not limited to, cancer, respiratory diseases, reproductive problems, birth defects, neurologic diseases, and developmental disorders;

(ii) characterize statewide and localized trends and geographic patterns in the occurrence of environmental hazards and exposures;

(iii) assess the feasibility of integrating disease rate

data with indicators of exposure to the selected environmental hazards such as biomonitoring data, and other health and environmental data;

(iv) incorporate newly collected and existing health tracking and biomonitoring data into efforts to identify communities with elevated rates of chronic disease, higher likelihood of exposure to environmental hazards, or both;

(v) analyze occurrence of environmental hazards, exposures, and diseases with relation to socioeconomic status, race, and ethnicity;

(vi) develop and implement targeted plans to conduct more intensive health tracking and biomonitoring among communities; and

(vii) work with the Pollution Control Agency, the Department of Agriculture, and other relevant state agency personnel and organizations to develop, implement, and evaluate preventive measures to reduce elevated rates of diseases and exposures identified through activities performed under sections 144.995 to 144.998; and

(6) submit a biennial report to the chairs and ranking members of the committees with jurisdiction over environment and health by January 15, beginning January 15, 2009, on the status of environmental health tracking activities and related research programs, with recommendations for a comprehensive environmental public health tracking program.

Subd. 2. **Biomonitoring.** The commissioner shall:

(1) conduct biomonitoring of communities on a voluntary basis by collecting and analyzing biospecimens, as appropriate, to assess environmental exposures to designated chemicals;

(2) conduct biomonitoring of pregnant women and minors on a voluntary basis, when scientifically appropriate;

(3) communicate findings to the public, and plan ensuing stages of biomonitoring and disease tracking work to further develop and refine the integrated analysis;

(4) share analytical results with the advisory panel and work with the panel to interpret results, communicate findings to the public, and plan ensuing stages of biomonitoring work; and

(5) submit a biennial report to the chairs and ranking members of the committees with jurisdiction over environment and health by January 15, beginning January 15, 2009, on the status of the biomonitoring program and any recommendations for improvement.

Subd. 3. **Health data.** Data collected under the biomonitoring program are health data under section 13.3805.

144.997 BIOMONITORING PILOT PROGRAM.

Subdivision 1. **Pilot program.** With advice from the advisory panel, and after the program guidelines in subdivision 4 are developed, the commissioner shall implement a biomonitoring pilot program. The program shall collect one biospecimen from each of the voluntary participants. The biospecimen selected must be the biospecimen that most accurately represents body concentration of the chemical of interest. Each biospecimen from the voluntary participants must be analyzed for one type or class of related chemicals. The commissioner shall determine the chemical or class of chemicals to which community members were most likely exposed. The program shall collect and assess biospecimens in accordance with the following:

(1) 30 voluntary participants from each of three communities that the commissioner identifies as likely to have been exposed to a designated chemical;

(2) 100 voluntary participants from each of two communities:

(i) that the commissioner identifies as likely to have been exposed to arsenic; and

(ii) that the commissioner identifies as likely to have been exposed to mercury; and

(3) 100 voluntary participants from each of two communities that the commissioner identifies as likely to have been exposed to perfluorinated chemicals, including perfluorobutanoic acid.

Subd. 2. **Base program.** (a) By January 15, 2008, the commissioner shall submit a report on the results of the biomonitoring pilot program to the chairs and ranking members of the committees with jurisdiction over health and environment.

(b) Following the conclusion of the pilot program, the commissioner shall:

(1) work with the advisory panel to assess the usefulness of continuing biomonitoring among members of communities assessed during the pilot program and to identify other communities and other designated chemicals to be assessed via biomonitoring;

(2) work with the advisory panel to assess the pilot program, including but not limited to the validity and accuracy of the analytical measurements and adequacy of the guidelines and protocols;

(3) communicate the results of the pilot program to the public; and

(4) after consideration of the findings and recommendations in clauses (1) and (2), and within the appropriations available, develop and implement a base program.

Subd. 3. **Participation.** (a) Participation in the biomonitoring program by providing biospecimens is voluntary and requires written, informed consent.

Minors may participate in the program if a written consent is signed by the minor's parent or legal guardian. The written consent must include the information required to be provided under this subdivision to all voluntary participants.

(b) All participants shall be evaluated for the presence of the designated chemical of interest as a component of the biomonitoring process. Participants shall be provided with information and fact sheets about the program's activities and its findings. Individual participants shall, if requested, receive their complete results. Any results provided to participants shall be subject to the Department of Health Institutional Review Board protocols and guidelines. When either physiological or chemical data obtained from a participant indicate a significant known health risk, program staff experienced in communicating biomonitoring results shall consult with the individual and recommend follow-up steps, as appropriate. Program administrators shall receive training in administering the program in an ethical, culturally sensitive, participatory, and community-based manner.

Subd. 4. **Program guidelines.** (a) The commissioner, in consultation with the advisory panel, shall develop:

(1) protocols or program guidelines that address the science and practice of biomonitoring to be utilized and procedures for changing those protocols to incorporate new and more accurate or efficient technologies as they become available. The commissioner and the advisory panel shall be guided by protocols and guidelines developed by the Centers for Disease Control and Prevention and the National Biomonitoring Program;

(2) guidelines for ensuring the privacy of information; informed consent; follow-up counseling and support; and communicating findings to participants, communities, and the general public. The informed consent used for the program must meet the informed consent protocols developed by the National Institutes of Health;

(3) educational and outreach materials that are culturally appropriate for dissemination to program participants and communities. Priority shall be given to the development of materials specifically designed to ensure that parents are informed about all of the benefits of breastfeeding so that the program does not result in an unjustified fear of toxins in breast milk, which might inadvertently lead parents to avoid breastfeeding. The materials shall communicate relevant scientific findings; data on the accumulation of pollutants to community health; and the required responses by local, state, and other governmental entities in regulating toxicant exposures;

(4) a training program that is culturally sensitive specifically for health care providers, health educators, and other program administrators;

(5) a designation process for state and private laboratories that are qualified to analyze biospecimens and report the findings; and

(6) a method for informing affected communities and local governments representing those communities concerning biomonitoring activities and for receiving comments from citizens concerning those activities.

(b) The commissioner may enter into contractual agreements with health clinics, community-based organizations, or experts in a particular field to perform any of the activities described under this section.

144.998 ENVIRONMENTAL HEALTH TRACKING AND BIOMONITORING ADVISORY PANEL.

Subdivision 1. **Creation.** The commissioner shall establish the Environmental Health Tracking and Biomonitoring Advisory Panel. The commissioner shall appoint, from the panel's membership, a chair. The panel shall meet as often as it deems necessary but, at a minimum, on a quarterly basis. Members of the panel shall serve without compensation but shall be reimbursed for travel and other necessary expenses incurred through performance of their duties. Members appointed by the commissioner are appointed for a three-year term and may be reappointed. Legislative appointees serve at the pleasure of the appointing authority.

Subd. 2. **Members.** (a) The commissioner shall appoint eight members, none of whom may be lobbyists registered under chapter 10A, who have backgrounds or training in designing, implementing, and interpreting health tracking and biomonitoring studies or in related fields of science, including epidemiology, biostatistics, environmental health, laboratory sciences, occupational health, industrial hygiene, toxicology, and public health, including:

(1) at least two scientists representative of each of the following:

(i) nongovernmental organizations with a focus on environmental health, environmental justice, children's health, or on specific chronic diseases; and

(ii) statewide business organizations; and

(2) at least one scientist who is a representative of the University of Minnesota.

(b) Two citizen panel members meeting the scientific qualifications in paragraph (a) shall be appointed, one by the speaker of the house and one by the senate majority leader.

(c) In addition, one representative each shall be appointed by the commissioners of the Pollution Control Agency and the Department of Agriculture,

and by the commissioner of health to represent the department's Health Promotion and Chronic Disease Division.

Subd. 3. **Duties.** The advisory panel shall make recommendations to the commissioner and the legislature on:

(1) priorities for health tracking;

(2) priorities for biomonitoring that are based on sound science and practice, and that will advance the state of public health in Minnesota;

(3) specific chronic diseases to study under the environmental health tracking system;

(4) specific environmental hazard exposures to study under the environmental health tracking system, with the agreement of at least nine of the advisory panel members;

(5) specific communities and geographic areas on which to focus environmental health tracking and biomonitoring efforts;

(6) specific chemicals to study under the biomonitoring program, with the agreement of at least nine of the advisory panel members; in making these recommendations, the panel may consider the following criteria:

(i) the degree of potential exposure to the public or specific subgroups, including, but not limited to, occupational;

(ii) the likelihood of a chemical being a carcinogen or toxicant based on peer-reviewed health data, the chemical structure, or the toxicology of chemically related compounds;

(iii) the limits of laboratory detection for the chemical, including the ability to detect the chemical at low enough levels that could be expected in the general population;

(iv) exposure or potential exposure to the public or specific subgroups;

(v) the known or suspected health effects resulting from the same level of exposure based on peer-reviewed scientific studies;

(vi) the need to assess the efficacy of public health actions to reduce exposure to a chemical;

(vii) the availability of a biomonitoring analytical method with adequate accuracy, precision, sensitivity, specificity, and speed;

(viii) the availability of adequate biospecimen samples; or

(ix) other criteria that the panel may agree to; and

(7) other aspects of the design, implementation, and evaluation of the environmental health tracking and biomonitoring system, including, but not limited to:

(i) identifying possible community partners and sources of additional public or private funding;

(ii) developing outreach and educational methods and materials; and

(iii) disseminating environmental health tracking and biomonitoring findings to the public.

Subd. 4. **Liability.** No member of the panel shall be held civilly or criminally liable for an act or omission by that person if the act or omission was in good faith and within the scope of the member's responsibilities under sections 144.995 to 144.998.

INFORMATION SHARING.

On or before August 1, 2007, the commissioner of health, the Pollution Control Agency, and the University of Minnesota are requested to jointly develop and sign a memorandum of understanding declaring their intent to share new and existing environmental hazard, exposure, and health outcome data, within applicable data privacy laws, and to cooperate and communicate effectively to ensure sufficient clarity and understanding of the data by divisions and offices within both departments. The signed memorandum of understanding shall be reported to the chairs and ranking members of the senate and house of representatives committees having jurisdiction over judiciary, environment, and health and human services.

Appendix B

How will participants be selected to be in the PFC Biomonitoring Project?
Participants will be selected through a specific recruitment process. In Oakdale, 500 households will be picked at random from a list of households served by the Oakdale city water supply. In Lake Elmo and Cottage Grove, MDH will contact all homes with PFCs in their private wells.

These households will be sent a letter about the study and a short survey. The survey will ask for the names of all adults age 20 or older who have lived in the home since before January 1, 2005. From the surveys that are sent back to MDH, 100 adults will be chosen at random from each of the two communities and asked to be part of the study.

Why does the study include only people who were in their current home before January 1, 2005?
The study includes only adults who have lived in their current home before January 1, 2005 to ensure that all of the people in the study were exposed to PFCs in the water. Starting in 2005, steps were taken to reduce people's exposure to PFCs in the water.

Why does the study include only adults?
The PFC Biomonitoring Project involves having blood drawn from a vein. This is an invasive medical procedure. Federal guidelines state that it is unethical to include children in this kind of research unless there is a clear benefit to them. Because there is no clear benefit to children being tested for PFCs, the PFC Biomonitoring Project will include only adults.

What will the people in the study have to do?
Each person who agrees to be part of the study will be asked to complete a short survey by phone. They will then need to go to the Woodwinds clinic in Oakdale or Woodbury to have 20 cc's (about 4 teaspoons) of their blood drawn.

When will the study results be available?
Because the process for measuring PFCs in the blood is complex, it may take up to three months for people in the study to receive their individual results. Results will be sent only to those who want to receive the results.

The results of the entire project will be ready in the spring of 2009. These results will provide a picture of the current levels of PFCs in people who drank water from the Oakdale city water supply and from private wells polluted with PFCs.

How did PFCs get into the water?
Wastes from the 3M Company that contained PFCs were disposed of in a number of landfills in the east metro area. The PFCs seeped into the groundwater and polluted many private wells as well as some city wells.

MINNESOTA MDH DEPARTMENT OF HEALTH

PFC Biomonitoring Project: Private Wells in Lake Elmo & Cottage Grove Overview

What are perfluorochemicals (PFCs)?
Perfluorochemicals (PFCs) are chemicals that have been used for many years to make products that resist heat, stains, grease and water.

Some products that are made using PFCs include:

- Nonstick cookware
- Carpets and fabrics that resist stains
- Foams for fighting fires
- Food wrappers

What is biomonitoring?
Biomonitoring means measuring the amount of a chemical in people's bodies. Chemicals are measured by taking a sample of someone's hair, urine, blood, or other body tissue. Scientists are able to measure chemicals in the body in very small amounts. But for most chemicals we do not know yet what the levels found in people's bodies mean for their health.

Why is the Minnesota Department of Health conducting the PFC Biomonitoring Project?
The Minnesota Department of Health (MDH) would like to learn about the levels of PFCs in people who have been exposed to PFCs in their drinking water. The PFC Biomonitoring Project will help us to learn the average levels of PFCs that people have in their bodies. We can then compare these levels to the PFC levels for the general population.

Why did I get this letter about the PFC Biomonitoring Project?
The Minnesota Department of Health (MDH) sent you this letter because our records indicate that your home's private well contains PFOA and/or PFOS at a level greater than 0.1 parts per billion.

How did PFCs get into the water?
Wastes from the 3M Company that contained PFCs were disposed of in a number of landfills in the east metro area. The PFCs seeped into the groundwater and polluted many private wells as well as some city wells.

Can PFCs harm people's health?
Very little is known about the human health effects of PFCs in the general population. Studies carried out by the 3M Company of workers who were exposed to PFCs during manufacturing show no apparent impact on their health. Studies on animals have shown some health effects, such as effects on the liver, thyroid, and pancreas. But it is unclear whether these problems are likely to occur in humans. Research into the effects that PFCs may have on people's health is new. It will take many years for scientists to learn whether there are links between PFCs and human health.

Who is eligible to be part of the PFC Biomonitoring Project?
In order to be in the study, people must live in one of the two communities that are part of the study. The first community is people who live in homes served by the Oakdale city water supply. The second community is homes in Lake Elmo and Cottage Grove with private wells where PFOA and/or PFOS have been found in the water at more than 0.1 parts per billion.

To be in the study, people must be age 20 or older. They also must have been living at their current home before January 1, 2005.

Why does the study include only people who were in their current home before January 1, 2005?
The study includes only adults who have lived in their current home before January 1, 2005 to ensure that all of the people in the study were exposed to PFCs in the water. Starting in 2005, steps were taken to reduce people's exposure to PFCs in the water.

Why does the study include only adults?
The PFC Biomonitoring Project involves having blood drawn from a vein. This is an invasive medical procedure. Federal guidelines state that it is unethical to include children in this kind of research unless there is a clear benefit to them. Because there is no clear benefit to children being tested for PFCs, the PFC Biomonitoring Project will include only adults.

How will people be chosen for the PFC Biomonitoring Project?
MDH will contact all homes with PFCs in their private wells. These homes will be sent a letter about the study and a short survey. The survey will ask for the names of all adults age 20 or older who have lived in the home since before January 1, 2005. From the surveys that are sent back to MDH, 100 adults will be chosen at random and asked to be part of the study.

What will the people in the study have to do?
Each person who agrees to be part of the study will be asked to complete a short survey by phone. They will then need to go to the Woodwinds clinic in Oakdale or Woodbury to have 20 cc's (about 4 teaspoons) of their blood drawn.

When will people get the study results?
Because the process for measuring PFCs in the blood is complex, it may take up to three months for people in the study to receive their results. Results will be sent only to those who want to receive the results.

The results of the entire project will be ready in the winter or spring of 2009. These results will provide a picture of the current levels of PFCs in people drinking water from private wells polluted with PFCs.

What will we learn from the PFC Biomonitoring Project?
The people who are part of the PFC study will have the chance to learn the levels of PFCs in their bodies. MDH will combine all of the results to provide an average, range, and distribution of the levels of PFCs for people drinking water from private wells polluted with PFCs.

Will the PFC Biomonitoring Project tell us about the health effects of PFCs?
The PFCs study will only tell us the levels of PFCs in people who drank water from private wells before January 1, 2005. The study will not be able to tell us whether PFCs caused anyone to get sick. That can only be learned from health studies that are beyond the scope of this project.

Will the PFC Biomonitoring Project tell us how these chemicals got into people's bodies?
There are many ways that people might be exposed to PFCs. Some ways that people might be exposed to PFCs include:

- The drinking water in the east metro area
- Food wrappers
- Household products
- Some jobs

The study will not be able to tell whether the PFCs in people's bodies came from the water or some other source.

For more information...
To learn more about this study, please contact Adrienne Kari at MDH at 651-201-3635 or adrienne.kari@state.mn.us.

Revised 8/6/08

Minnesota Department of Health
PFC Biomonitoring Project Questionnaire

Household ID# _____

Thank you for taking a few minutes to complete this brief survey. The information we are collecting will be used to gather information about drinking water used by people living in your community. We will also compile a list of adults, 100 of whom will be *randomly* selected and invited into the biomonitoring study. Completing this survey does not enroll you or someone in your household in the study, and you are not required to provide this information. However, if you choose not to provide the information requested below than it will not be possible for you or anyone in your household to be chosen and invited to participate in the study. This information will be protected by MDH and is private data under Minnesota law.

Please provide the following information for a primary contact for your household:

Name (print):_____ _____phone number(s):_____(home) _____(work) _____(cell)
First Last

What is the best time of day and phone number to reach you by phone:_____
Please confirm the current mailing address:_____
Street City State Zip

The following question is in regards to the *current* drinking water source used in the home.

1. What, if any, water filter or treatment device(s) is your household currently using? (please check all that apply)

☐ none, no filter or treatment device used
☐ under the sink carbon filter*
☐ reverse osmosis (RO) system
☐ pitcher filter (i.e. Brita, Pur, etc.)
☐ whole house carbon filter*
☐ kitchen faucet filter
☐ none; use bottled water only
☐ other, please describe:_____
☐ refrigerator filter
☐ not sure

*Carbon filter may be called a Granular Activated Carbon or GAC filter.

2. Do you know the recommended schedule for changing your water filter?
☐ Yes ☐No
If Yes: How often do you change it? _____

The following question is in regards to all adults who are residents in the household.

3. How many adults (Age 20 and older) are currently living at this household? _____
3a. How many of the adults (Age 20 and older) were living there before Jan. 1, 2005?_____
If your answer to 3A above is zero (no adults lived in the home prior to Jan. 1, 2005), then please return this form in the envelope provided. This completes your survey. **Otherwise, please complete the table on the next page.**

p. 69

Please fill out the following table for all the eligible adults you included in the response to question 3.

Full Name First and Last	Date of Birth 00/00/0000	Telephone Number(s) where this adult can be reached	When did this adult first come to live at this current address?	Gender
a. _____	___/___/___ Mo/Day/Year	(home): _____ (work): _____ (cell): _____	___/___/___ Mo/Day/Year	☐ Male ☐ Female
b. _____	___/___/___ Mo/Day/Year	(home): _____ (work): _____ (cell): _____	___/___/___ Mo/Day/Year	☐ Male ☐ Female
c. _____	___/___/___ Mo/Day/Year	(home): _____ (work): _____ (cell): _____	___/___/___ Mo/Day/Year	☐ Male ☐ Female
d. _____	___/___/___ Mo/Day/Year	home): _____ (work): _____ (cell): _____	___/___/___ Mo/Day/Year	☐ Male ☐ Female
e. _____	___/___/___ Mo/Day/Year	home): _____ (work): _____ (cell): _____	___/___/___ Mo/Day/Year	☐ Male ☐ Female

Name of person completing this survey: _____ date: _____

Thank you for completing this survey and returning it to us in the envelope provided. If a member of your household is selected, he or she will receive a letter inviting them to participate in the study, more detailed information, and a consent form. If you have questions feel free to contact Adrienne Kari, Minnesota Department of Health at 651-201-2936.

p.67

Si usted preferiría estos materiales en español llaman por favor 651-201-3635

July 17, 2008

<First Name> <Last Name>
<Address>
<Address2>
<City>, <State> < Zip>

Dear <First Name> <Last Name>:

The Minnesota Department of Health (MDH) is doing a study to measure the levels of perfluorochemicals (PFCs) in people's bodies. This testing is part of the biomonitoring program at MDH. Biomonitoring means measuring how much of the chemicals around us have gotten into people's bodies. (Please see the enclosed fact sheet for more details.)

The MDH PFC study will measure PFCs in 100 adults age 20 and over. We are writing to you about this study because MDH records show that your well was polluted with low levels of PFCs disposed of by 3M. The study will only include people who have been living at their current address since before January 1, 2005. This will ensure that the people in the study were all exposed to the PFCs before water treatments and alternative water supplies were put into place.

We are sending you this letter to find out how many of the adults in your home are eligible to be part of the study. Please fill out the enclosed form and mail it to MDH in the envelope supplied.

Filling out this form does not require anyone in your home to be in the study. It will just help us to find out who is eligible to be in the study. All information that identifies the people in your home will be kept private.

From all of the forms MDH receives, 100 adults will be picked at random and asked to be in the study. Those 100 adults will be sent a letter that will explain the study in more detail. The letter will also ask them to be in the study. If someone from your house is invited to be in the study, they can choose whether or not they want to be in the study.

People in the study will be asked to go to a nearby clinic to have 20 cc's (about 4 teaspoons) of blood drawn. The blood will be tested for a number of PFCs. Each person that is in the study will be given the choice to have their own test results (PFC levels in the blood) mailed to them or not. All costs for the blood draw and PFC analysis will be covered by MDH.

Thank you for taking the time to read this letter and for filling out the enclosed form. Please call me at (651) 201-3635 or email me at adrienne.kari@state.mn.us if you have any questions about the study. We look forward to hearing from you.

Sincerely,

Adrienne Kari

Adrienne Kari, M.P.H.
Biomonitoring Coordinator
Minnesota Department of Health

Si usted preferiría estos materiales en español llaman por favor 651-201-3635

PFC Biomonitoring Project: Oakdale Overview

What are perfluorochemicals (PFCs)?
Perfluorochemicals (PFCs) are chemicals that have been used for many years to make products that resist heat, stains, grease and water.

Some products that are made using PFCs include:

- Nonstick cookware
- Carpets and fabrics that resist stains
- Foams for fighting fires
- Food wrappers

What is biomonitoring?
Biomonitoring means measuring the amount of a chemical in people's bodies. Chemicals are measured by taking a sample of someone's hair, urine, blood, or other body tissue. Scientists are able to measure chemicals in the body in very small amounts. But for most chemicals we do not know yet what the levels found in people's bodies mean for their health.

Why is the Minnesota Department of Health conducting the PFC Biomonitoring Project?
The Minnesota Department of Health (MDH) would like to learn about the levels of PFCs in people who have been exposed to PFCs in their drinking water. The PFC Biomonitoring Project will help us to learn the average levels of PFCs that people have in their bodies. We can then compare these levels to the PFC levels for the general population.

Why did I get this letter about the PFC Biomonitoring Project?
As you may know, the Oakdale city water supply that serves your home was polluted with PFCs. Your address was one of 500 households picked at random from a list of Oakdale city water supply customers.

How did PFCs get into the water?
Wastes from the 3M Company that contained PFCs were disposed of in a number of landfills in the east metro area. The PFCs seeped into the groundwater and polluted many private wells as well as some city wells.

Can PFCs harm people's health?
Very little is known about the human health effects of PFCs in the general population. Studies carried out by the 3M Company of workers who were exposed to PFCs during manufacturing show no apparent impact on their health. Studies on animals have shown some health effects, such as effects on the liver, thyroid, and pancreas. But it is unclear whether these problems are likely to occur in humans. Research into the effects that PFCs may have on people's health is new. It will take many years for scientists to learn whether there are links between PFCs and human health.

Who is eligible to be part of the PFC Biomonitoring Project?
In order to be in the study, people must live in one of the two communities that are part of the study. The first community is people who live in homes served by the Oakdale city water supply. The second community is homes in Lake Elmo and Cottage Grove with private wells where PFOA and/or PFOS have been found in the water at more than 0.1 parts per billion.

To be in the study, people must be age 20 or older. They also must have been living at their current home before January 1, 2005.

Why does the study include only people who were in their current home before January 1, 2005?
The study includes only adults who have lived in their current home before January 1, 2005 to ensure that all of the people in the study were exposed to PFCs in the water. Starting in 2005, steps were taken to reduce people's exposure to PFCs in the water.

Why does the study include only adults?
The PFC Biomonitoring Project involves having blood drawn from a vein. This is an invasive medical procedure. Federal guidelines state that it is unethical to include children in this kind of research unless there is a clear benefit to them. Because there is no clear benefit to children being tested for PFCs, the PFC Biomonitoring Project will include only adults.

How will people be chosen for the PFC Biomonitoring Project?
Five hundred households will be picked at random from a list of households served by the Oakdale city water supply. These households will be sent a letter about the study and a short survey. The survey will ask for the names of all adults age 20 or older who have lived in the home since before January 1, 2005. From the surveys that are sent back to MDH, 100 adults will be chosen at random and asked to be part of the study.

What will the people in the study have to do?
Each person who agrees to be part of the study will be asked to complete a short survey by phone. They will then need to go to the Woodwinds clinic in Oakdale or Woodbury to have 20 cc's (about 4 teaspoons) of their blood drawn.

When will people get the study results?
Because the process for measuring PFCs in the blood is complex, it may take up to three months for people in the study to receive their results. Results will be sent only to those who want to receive the results.

The results of the entire project will be ready in the winter or spring of 2009. These results will provide a picture of the current levels of PFCs in people drinking water from the Oakdale city water supply.

What will we learn from the PFC Biomonitoring Project?
The people who are part of the PFC study will have the chance to learn the levels of PFCs in their bodies. MDH will combine all of the results to provide an average, range, and distribution of the levels of PFCs for people drinking Oakdale city water.

Will the PFC Biomonitoring Project tell us about the health effects of PFCs?

The PFCs study will only tell us the levels of PFCs in people who drank water from the Oakdale city water supply before January 1, 2005. The study will not be able to tell us whether PFCs caused anyone to get sick. That can only be learned from health studies that are beyond the scope of this project.

Will the PFC Biomonitoring Project tell us how these chemicals got into people's bodies?

There are many ways that people might be exposed to PFCs. Some ways that people might be exposed to PFCs include:

- The drinking water in the east metro area
- Food wrappers
- Household products
- Some jobs

The study will not be able to tell whether the PFCs in people's bodies came from the water or some other source.

For more information...

To learn more about this study, please contact Adrienne Kari at MDH at 651-201-3635 or adrienne.kari@state.mn.us.

Minnesota Department of Health

PFC Biomonitoring Project Questionnaire

Household ID# _____

Thank you for taking a few minutes to complete this brief survey. The purpose of the survey is to gather information about the drinking water used by people living in Oakdale. We will also compile a list of adults, 100 of whom will be *randomly* selected and invited into the biomonitoring study. Completing this survey does not enroll anyone in your household in the study. You are not required to provide this information. However, if you choose not to provide this information it will not be possible for anyone in your household to be chosen and invited to participate in the study. The information you provide on this survey is private and will be protected by MDH according to Minnesota law.

Please provide the following information for a primary contact for your household:

Name (print):_____ _____phone number(s):_____(home) _____(work) _____(cell)
First Last

What is the best time of day and number to reach you by phone:_____

Please confirm the current mailing address:_____
Street City State Zip

The following questions are about the *current* drinking water source used in the home.

2. What, if any, water filter or treatment device(s) is your household currently using? (please check all that apply)

☐ none, no filter or treatment device used
☐ under the sink carbon filter*
☐ reverse osmosis (RO) system
☐ pitcher filter (i.e. Brita, Pur, etc.)
☐ whole house carbon filter*
☐ kitchen faucet filter
☐ none; use bottled water only
☐ other, please describe:_____
☐ refrigerator filter
☐ not sure

*Carbon filter may be called a Granular Activated Carbon or GAC filter.

2. Do you know the recommended schedule for changing your water filter?
☐ Yes ☐No

If Yes: How often do you change it? _____

The following question is about all adults who are residents in the household.

3. How many adults (age 20 and older) are currently living at this household? _____
3a. How many of these adults (age 20 and older) were living there before Jan. 1, 2005? _____

If your answer to question 3A is zero (no adults lived in this home prior to Jan. 1, 2005), then please return this form in the envelope provided. This completes your survey. **Otherwise, please complete the table on the next page.**

2. Please fill out the following table for all adults age 20 and over (including yourself) currently living in your household at this address.

Full Name First and Last	Date of Birth 00/00/0000	Telephone number(s) where this adult can be reached.	When did this adult first come to live at this current address?	Approximately how many years <u>total</u> of his/her life has this adult lived in Oakdale (at any address)?	Gender
a. _____	___/___/_____ Mo/Day/Year	(home):_____ (work):_____ (cell):_____	___/_____ Mo/Year		☐ Male ☐ Female
b. _____	___/___/_____ Mo/Day/Year	(home):_____ (work):_____ (cell):_____	___/_____ Mo/Year		☐ Male ☐ Female
c. _____	___/___/_____ Mo/Day/Year	(home):_____ (work):_____ (cell):_____	___/_____ Mo/Year		☐ Male ☐ Female
d. _____	___/___/_____ Mo/Day/Year	(home):_____ (work):_____ (cell):_____	___/_____ Mo/Year		☐ Male ☐ Female
e. _____	___/___/_____ Mo/Day/Year	(home):_____ (work):_____ (cell):_____	___/_____ Mo/Year		☐ Male ☐ Female

Name of person completing this survey: _____ date: _____

Thank you for completing this survey and returning it to us in the envelope provided. If a member of your household is selected, he or she will receive a letter inviting them to participate in the study, more detailed information about the study, and a consent form. If you have questions feel free to contact Adrienne Kari, Minnesota Department of Health, at 651-201-3635.

Si usted preferiría estos materiales en español llaman por favor 651-201-3635

Date

Name
Address

Dear Name

The Minnesota Department of Health (MDH) is doing a study to measure the levels of perfluorochemicals (PFCs) in people's bodies. This testing is part of the biomonitoring program at MDH. Biomonitoring means measuring how much of the chemicals around us have gotten into people's bodies. (Please see the enclosed fact sheet for more details.)

The MDH study will measure PFCs in 100 Oakdale adults age 20 and over. We are writing to you about this study because the Oakdale city water supply that serves your home was polluted with low levels of PFCs disposed of by 3M. The study will only include people who have been living at their current address since before January 1, 2005. This will ensure that the people in the study were all exposed to the PFCs before changes were made to how the city's water was treated and managed.

We are sending you this letter to find out how many of the adults in your home are eligible for the study. Please fill out the enclosed form and mail it to MDH in the envelope supplied.

Filling out this form does not require anyone in your home to be in the study. It will just help us to find out who is eligible to be in the study. All information that identifies the people in your home will be kept private.

From all of the forms MDH receives, 100 adults will be picked at random and asked to be in the study. Those 100 adults will be sent a letter that will explain the study in more detail. The letter will also ask them to be in the study. If someone from your house is invited to be in the study, they can choose whether or not they want to be in the study.

People in the study will be asked to go to a nearby clinic to have 20 cc's (about 4 teaspoons) of blood drawn. The blood will be tested for a number of PFCs. Each person that is in the study will be given the choice to have their own test results (PFC levels in the blood) mailed to them or not. All costs for the blood draw and PFC lab analysis will be covered by MDH.

Thank you for taking the time to read this letter and for filling out the enclosed form. Please call me at (651) 201-3635 or email me at adrienne.kari@state.mn.us if you have any questions about the study. We look forward to hearing from you.

Sincerely,

Adrienne Kari

Adrienne Kari, M.P.H.
Biomonitoring Coordinator
Minnesota Department of Health

Si usted preferiría estos materiales en español llaman por favor 651-201-3635

Appendix C

Date

<First Name> <Last Name>
<Address>
<Address2>
<City>, <State> <Zip Code>

Dear <First Name> <Last Name>,

The Minnesota Department of Health recently mailed a letter to your home with information about a study to measure the levels of perfluorochemicals (PFCs) in people's bodies. A person in your household filled out a survey about the adults living in your home. We randomly selected people from all the returned surveys to take part in our study. Your name was selected, and at this time we would like to invite you to join the study.

This study is a pilot project being conducted at the Minnesota Department of Health (MDH). This study will give us information about current PFC levels in people living in Oakdale, Cottage Grove and Lake Elmo. This study will also help us learn about the best ways to gather information on the chemicals in people's bodies.

Please read the consent forms included with this letter. If you have any questions, please contact Adrienne Kari at 651-201-3635. If you agree to be a part of the study, please sign, date, and return the forms to MDH in the envelope provided. Please keep one copy of these forms for your records.

To be in the study you must have 20 cc's, or about 4 teaspoons, of blood drawn. You will need to set up an appointment at the Woodwinds clinic in Oakdale or Woodbury to have your blood drawn. Once we receive your signed consent forms, we will send you detailed instructions on how to set up your appointment. We will also send you a set of labels. You will need to bring these labels with you to your appointment. The clinic will collect your blood and the MDH lab will do the tests to measure the levels of PFCs in your blood.

You will receive a letter with the results of the PFC tests. It may take up to three months for you to receive your results. The delay is because the lab method used to test for PFCs is complicated. The letter with your results will give you a list of all of the PFCs tested for and the levels that were found in your blood. For some of the PFCs we will be able to compare your results to the U.S. general population. For other PFCs that the lab may measure there are no national levels that we can compare results to.

At the end of the study you will receive a letter telling you about the results of the entire study. You will then be able to compare your own results to the community as a whole. You will also receive a $20 gas gift card to compensate you for your travel cost to the clinic.

Thank you for being a part of this important study. A member of our study staff will contact you by phone in about two weeks. In the meantime, if you have any questions or concerns please contact me at 651-201-3635 or adrienne.kari@state.mn.us.

Sincerely,

Adrienne Kari, M.P.H.
Biomonitoring Coordinator
Minnesota Department of Health

Participant ID

Minnesota Department of Health

PFC Biomonitoring Project
Consent Form

Introduction: You are invited to be a part of a research study. The study will measure the levels of perfluorochemicals (PFCs) in people's bodies. You have been asked to be in this study because you live in an area where there are PFCs in the drinking water. Please read this form before you agree to be in the study. You may call 651-201-3635, to ask any questions before you agree to be in the study.

The PFC Biomonitoring Project will be carried out by staff at the Minnesota Department of Health (MDH).

Purpose: There are two goals for this study. The first goal is to measure the levels of PFCs in the blood of people who drank water with PFCs in it. This includes people who drank water from the Oakdale city water supply or from private wells that had PFCs in them. The study will compare the PFC levels of these people to the PFC levels of other people around the country.

The second goal is to learn about the best way to conduct this type of study again in the future.

Procedures: If you agree to be a part of this study, the study staff will call you to do a short survey. We will ask you to go to the Woodwinds clinic in Oakdale or Woodbury to have 20 cc's (about 4 teaspoons) of blood drawn. We will send you directions for how to get your blood drawn. We will also send you labels to bring with you to your clinic visit. These labels will be placed on your blood sample. The label will have only a code on it. Only the study coordinator will know whose blood sample it is. The blood sample will be taken to the MDH lab to measure the levels of PFCs. If you would like to receive your results, we will send them to you in a letter. It may take up to three months before you get your results in the mail. All costs for the blood draw and PFC lab analysis will be covered by MDH.

Stored Blood Samples: The blood you provide for the study will be used to test for PFCs in your body. Any blood that is not needed for the PFC test will be stored at the MDH lab for the length of the study. The blood will be saved during this time in case the lab needs to repeat the test to check the accuracy of the result. There is a separate consent form included with this consent asking you to allow us to store your blood for future research.

Participant ID

Risks of Being in the Study: This study requires a blood draw. You may feel a sharp sting from the needle used to draw your blood. Sometimes a bruise or small blood clot appears at the site. These bruises or clots usually go away on their own. Putting heat on the site can also help the bruise or clot to go away. Although it rarely happens, the needle could cause damage to a nerve. This nerve damage can cause numbness in part of the arm. You or your insurance company are responsible for any follow-up care if you are injured as a result of being in this study. If you think you have had an injury as a result of being in the study please let the study staff know right away. Some people may feel worried about having their blood drawn. If having your blood drawn will cause you too much worry, you should not be a part of the study.

With your consent, we will send you a letter with your test results. Some people may feel worried about their results. There is little we can tell you about what your results mean for your health. This study will only tell you about the levels of PFCs in your blood and how your levels compare to other people in the country.

Benefits of Being in the Study
At the end of the study you will be sent a letter with the results of the whole study. You will also receive your own results if you choose to receive them. You will be able to call the MDH staff during and after the study if you have any questions. If your doctor has questions about PFCs, he or she may also call the MDH staff. The names and phone numbers of people to call are listed below.

MDH will provide all of the people in the study with information on water treatment systems that can reduce exposure to PFCs. For private well owners we will provide information about well testing.

Confidentiality: All individual data and personal information gathered for the study is private. This information is protected by Minnesota law. Only members of the research study team will have access to information that can identify you. You are the only one who will receive your own results. All of the information we collect for this study will be stored safely in a secure area. The information will be kept in a password-protected and locked database or file at all times. At the end of the study, MDH will share the study summary results with you and your community. The summary will combine all of the data together. No information that could identify you will be included in any reports about this study.

Voluntary Participation: You can decide whether or not you want to be a part of the study. Your choice will not affect your current or future relationships with MDH or other groups that are part of the study. If you decide to be a part of the study, you are free to quit the study at any time. If the study staff decides it is in your best interest, or if you fail to meet the study requirements, you may be removed from the study without your consent.

Participant ID

PFC Stored Blood Consent

This consent is to allow any blood that is not used to measure PFCs to be used in future research. Please read this form before marking yes or no.

Stored blood may be used for these or other types of research:

- To develop new lab methods to measure chemicals in blood
- To serve as control samples
- For other biomonitoring studies

Stored blood will not be used for genetic research, as defined by Minnesota law, unless we contact you first.

The stored blood will be labeled only with a code. Only the staff of the MDH biomonitoring program will have information that could identify you.

You will not be told about any future research. You will not receive results from any other tests done on the blood.

After the PFC study is over you may ask that the sample be destroyed. Requests should be sent to:

Chronic Disease and Environmental Epidemiology
Minnesota Department of Health
PO Box 64882
St. Paul, MN 55164-0882.

Contacts and Questions: If you have any questions, you can call or email the study staff.

Adrienne Kari
Study Coordinator
651-201-3635 or 1-888-345-0823
adrienne.kari@state.mn.us

Dr. Jean Johnson
Program Director
651-201-5902 or 1-888-345-0823
jean.johnson@state.mn.us

If you have questions or concerns about the study or your rights as a research participant, and you would like to talk to someone other than the study staff, you may contact Peter Rode of the MDH Institutional Review Board at (651) 201-5942.

I agree that my sample may be stored at MDH and used for future research. I understand that I will not be told of that use or the results.

☐ **yes** ☐ **no**

Participant's Name:_____
(printed)

Participant's Signature:_____

Date Signed:_____

Study Coordinator Signature:_____

MDH IRB Approval #08-196 Revised on November 25, 2008
HE IRB Approval #08 06 002

Participant Study ID number

PFC Biomonitoring Project
Phone Call Survey

[Once a signed consent has been received the letter detailing which clinic to call and a set of labels for the blood sample will be mailed out to the participant. A phone call will also be made to reiterate the instructions in that letter and to obtain some demographic information not obtained in the recruitment survey.]

MDH: Very briefly I have a short set of questions that I need to ask to complete our questionnaire for the study. This information will be kept private, if at any time you feel uncomfortable you do not have to answer the questions.

1. Have you ever worked at 3M? ☐Yes ☐ No

   If No skip to question 2.

   1a. Have you ever worked in Perfluorochemical Research or in a Perfluorochemical Research Facility?
   ☐Yes ☐ No

   1b. Have you ever worked in Perfluorochemical production facility including 3M Cottage Grove?
   ☐Yes ☐ No

2. What type of water do you typically drink?
   - ☐ unfiltered tap water
   - ☐ filtered tap water
   - ☐ bottled water
   - ☐ other

3. What, if any, water filter or treatment device(s) are you currently using for drinking and cooking? (mark all that apply)
   - ☐ none, no filter or treatment device used
   - ☐ whole house carbon filter*
   - ☐ none; use bottled water only.
   - ☐ under the sink carbon filter*
   - ☐ kitchen faucet filter
   - ☐ reverse osmosis (RO) system
   - ☐ pitcher filter (i.e. Britta, Pur, etc.)
   - ☐ not sure
   - ☐ other, please describe:_____

4. How would you describe your ethnicity?
   - ☐ Non-Hispanic White
   - ☐ Non-Hispanic Black
   - ☐ Chicano/Latino
   - ☐ Asian-American
   - ☐ Native American
   - ☐ Other
   - ☐ I prefer not to say

If Participant is female:

5. Are you currently pregnant?
   ☐Yes ☐ No

   If no skip to 6

   5a. Are you more than 7 months pregnant? ☐Yes ☐ No
   (verify this won't interfere with completing study)

6. Do you have any health conditions that would prevent you from having your blood drawn for the study?
   ☐Yes ☐ No

7. How would you describe your health?
   ☐ Very Good ☐ Good ☐ Bad ☐ Very Bad

That concludes my short survey.

To complete the blood draw you will need to go to either the Woodbury or Oakdale Woodwinds clinic. To schedule your appointment at the Woodbury clinic you'll need to call 651-232-6700, the clinic hours are from 8:00 am to 4:30pm. To schedule your appointment at the Oakdale clinic you'll need to call 651-326-5300, the clinic hours are from 8:00am to 4:30pm. When you call to make your appointment please be sure to tell them that the appointment will be for the Minnesota Department of Health PFC study.

You will be receiving a letter in the mail with directions to the clinics as well as a set of labels for your blood sample. Please remember to bring these materials with you to your clinic visit.

Do you have any questions about the study for me?

And don't forget to look for the letter we have mailed out with the instructions and labels for your blood draw. Please, don't hesitate to call us with any questions or concerns.

Thanks for your time!

Date

[First Name][Last Name]
[Address]
[Address 2]
[City], [State] [Zip]

Dear [First Name],

Thank you for agreeing to participate in the study and returning the consent materials. To complete the study you will need to have your blood drawn at a local clinic and answer a few brief questions with one of our MDH staff.

If they have not already done so a member of MDH staff will be calling you to give you directions on where to go to have your blood drawn and answer any questions you might have about the study. During that phone call they will also ask you a few brief questions. You may also ask any questions that you have about the study.

To complete the blood draw you will need to make an appointment at either the Woodbury or Oakdale HealthEast clinics. The HealthEast Woodbury clinic is located at 1875 Woodwinds Drive, Woodbury MN 55125, please call 651-232-6700 to make an appointment. The Oakdale HealthEast clinic is located at 1099 Helmo Ave NE, Suite 100, Oakdale, MN 55128 , please call 651-326-5300 to make an appointment. You are free to go to either clinic; you only need to go to one clinic to have your blood drawn. Please go to the clinic that is most convenient for you.

Included with this letter are the labels that will be attached to your blood sample. Please bring the labels and this letter with you to your appointment at either HealthEast clinic. MDH staff will pick up your blood sample from the HealthEast clinic and bring it to the MDH laboratory for analysis. You will receive the results from the analysis within three months, if you agreed to receive the results on your consent form. If you have any questions please call me at 651-201-3635 or email me at Adrienne.kari@state.mn.us.

Again, thank you very much for your time and participation in the study!

Sincerely,

Adrienne Kari

Adrienne Kari, MPH
Biomonitoring Coordinator
Minnesota Department of Health

Appendix D

Date

Address

Dear <Name>,

Thank you for being a part of the Minnesota Department of Health's Perfluorochemicals (PFCs) Biomonitoring Study. We are grateful for the time and effort you gave to the study.

This letter is to give you your results. The table below shows the levels of PFCs found in your blood. The table also shows the average levels and ranges for the United States, when known.

Perfluorochemical (PFC)	Your Level (ng/mL)	U.S. Population* Average Level (ug/L)	U.S. Population* Range (ug/L) 10^{th} to the 95^{th} percentile
PFOA		3.9	1.9 – 9.8
PFOS		20.7	9.8 – 54.6
PFBA		**	**
PFHxS		1.9	0.7 – 8.3
PFBS		**	**
PFHxA		**	**
PFPeA		**	**

* The levels for the U.S population are based on results from the National Health and Nutrition Examination Survey (NHANES). NHANES results are from a random sample of the U.S. population (age 12 and greater) taken in years 2003-2004.
**NHANES does not report an average or range for this chemical.

Just because people have a chemical in their blood does not mean that the chemical causes disease. Research on PFCs and people's health is new. So far, research has not shown an increase in the risk for disease from being exposed to PFCs. (Please see the enclosed booklet for more information about PFCs and health.)

Once we have analyzed all of the data, we will send you the study results. This will allow you to see how your PFC levels compare to the PFC levels found in the community as a whole.

If you or your doctor have any questions about these results or wish to further discuss these results, please call me at 651-201-3635.

Thank you again for being part of MDH's PFC Biomonitoring Study.

Sincerely,

Adrienne Kari
Biomonitoring Coordinator
Minnesota Department of Health

What are PFCs?

Perfluorochemicals (PFCs) are chemicals that have been used for many years to make products that resist heat, stains, grease and water.

Some products that may be made using PFCs include:

- Nonstick cookware
- Furniture and carpets that are treated to resist stains
- Clothing that is treated to resist stains or repel water
- Foams for fighting fires
- Fast food wrappers or packaged food containers, such as French fry boxes, pizza boxes, hamburger wrappers, and microwave popcorn bags
- Makeup and personal care products, such as dental floss, pressed powders, nail polish and shaving cream with ingredients that have 'perfluoro' in the name

There are many kinds of PFCs. The seven that were tested for in the PFC biomonitoring study include:

- PFOS Perfluorooctane sulfonate
- PFOA Perfluorooctanoic acid
- PFHxS Perfluorohexane sulfonate
- PFHxA Perfluorohexanoic acid
- PFPeA Perfluoropentanoic acid
- PFBA Perfluorobutyric acid
- PFBS Perfluorobutane sulfonate

The two PFCs that researchers know the most about are PFOS and PFOA. There is less known about the other PFCs that have been found in the drinking water in the east metro area and in people's bodies around the world. The information in this booklet is mostly about PFOS and PFOA.

What does my PFC test result mean?

The PFC test measures the amounts of PFCs that are in your blood. The test results reflect your past and current exposure to PFCs.

Some PFCs, such as PFBA, leave the body quickly, in a matter of days. For PFBA, the level measured in the blood reflects exposure that you have had in the last few days. Other PFCs, such as PFOA and PFOS, stay in the body for a number of years. For these chemicals, the test result reflects your total exposure over the past few years. Your test results reflect exposure to PFCs from all of the sources that you may have been in contact with during that time period.

Biomonitoring results on their own do not tell us about the health effects that people might have from being exposed to chemicals. In order to learn about the health effects linked to different levels of exposure to chemicals, information from biomonitoring studies must be combined with information from health studies.

With some chemicals that can be measured in the body, enough research has been done that we know what levels are safe and what levels are unsafe. For PFCs, we do not yet know enough to say whether there are levels in the blood that are safe or unsafe. However, based on current research, levels of PFCs found in the general population and in workers have not been shown to increase people's risk for disease.

Do PFCs cause health problems?

Studies on animals have found that PFCs may affect animals' health in some ways. In animals, being exposed to PFCs at high doses can cause changes in the function of the liver, thyroid and pancreas. In animals, PFCs may also cause changes to hormone levels.

In humans, research has not conclusively shown that PFCs are related to specific diseases or health effects. Studies of workers have looked for effects on cholesterol levels, male reproductive hormones, and heart disease. So far, these studies have not consistently shown that PFC exposure is linked to these health problems.

Most of the research on humans so far has been done with people who were exposed to PFCs on the job. The PFOS and PFOA levels that workers are exposed to are higher than what the general population is exposed to.

Many of the studies, because they focus on workers exposed to PFCs on the job, do not include women or children.

Further research is needed to learn more about what, if any, health effects may be linked with PFCs. A full report about the current research on PFCs and health can be found at www.health.state.mn.us/divs/eh/hazardous/sites/washington/3mcg0205.pdf.

Do PFCs cause cancer?

Studies on animals have found that PFCs may be linked with an increase in the risk of cancer of the liver, pancreas, and testes. However, so far studies of humans do not show conclusive results that PFCs are linked to cancer. Studies of workers have looked at whether PFCs are linked with prostate, bladder, and liver cancer. So far none of these studies have found a link between PFCs and cancer.

Is there more cancer in the east metro area?

The Minnesota Cancer Surveillance System at MDH did a study of cancers in Dakota and Washington Counties for 1988 to 2004. Looking at all kinds of cancer together, the cancer rates in Washington and Dakota Counties are very similar to the rest of the state.

When looking at the rates of specific kinds of cancers, most rates were about the same as the rest of the state. A few rates were higher and a few were lower than the rest of the state. These kinds of differences are very common across communities.

The study also looked at cancer rates for the years 1996 to 2004 in eight specific cities where PFCs were found in the water. These rates were then compared to the rates in the whole metro area. In these eight cities combined, the overall cancer rates, as well as rates for 16 specific cancers, are almost exactly the same as the rates for the whole metro area.

For a number of reasons, including the fact that many people move in and out of the area and the long time that it can take for cancer to develop, cancer rates are not a good way to judge whether the water pollution has had any effect on cancer rates.

A full report of the study can be found online at www.health.state.mn.us/divs/hpcd/cdee/mcss/documents/dakotawashingtoncancerreport.pdf.

Should other members of my family get tested for PFCs?

MDH does not advise that everyone get their PFC levels tested. The test can be very costly. The test also cannot predict whether someone will have any health problems from being exposed to PFCs.

There is no treatment that can remove the PFCs from the body. The only way to remove PFCs from the body is over time through the urine and feces.

If you choose to have yourself or others in your family tested, there are two private labs that can perform the PFC test. MDH does not endorse any lab for PFC testing.

AXYS:
1-800-373-0881
www.axysanalytical.com/services/

MPI Research, Inc:
1-814-272-1039
www.mpiresearch.com/

Where can I get more information?

For more information about PFCs and Minnesota please visit:

www.health.state.mn.us/divs/eh/hazardous/topics/pfcs

References

1. A Calafat et al. "Polyfluoroalkyl Chemicals in the U.S. Population: Data from the National Health and Nutrition Examination Survey (NHANES) 2003–2004 and Comparisons with NHANES 1999–2000" *Environmental Health Perspectives.* 115:1596–1602 (2007)

2. G. Olsen, J Burris, M Burlew, and J Mandel. "Epidemiologic Assessment of Worker Serum Perfluorooctanesulfonate (PFOS) and Perfluorooctanoate (PFOA) Concentrations and Medical Surveillance Examinations." *Journal of Occupational and Environmental Medicine.* 45(3): 260-270 (2003)