In late January 2008, the Minnesota Department of Health held three community meetings to share plans for a biomonitoring pilot project to measure PFCs in people’s bodies. This document provides a summary of the answers to community members’ questions about the project.

**Purpose/scope of the biomonitoring project**

The biomonitoring pilot project will help understand what levels of PFCs are getting into people’s bodies. We currently know what the levels of PFCs are in the water, but we do not yet know what the levels are in the people who have been drinking that water. The biomonitoring pilot project will provide information to help inform decisions about additional research and actions that should be taken. For the pilot project, detailed information about health and possible sources of exposure will not be gathered.

*What types of information will be collected from participants? Will MDH collect information on the length of time a person has been at their residence?*

Participants will be asked to complete a brief questionnaire, which will likely gather information to determine their age, length of time living at their current residence, current drinking water source, current use of alternative water supplies and/or water treatment devices, gender, ethnicity, and potential occupational exposure to PFCs at 3M. Participants will also be asked to provide their names and phone numbers so that they can be contacted by project staff, if needed.

*Shouldn’t a health history be collected from each participant in order to understand the numbers collected through the biomonitoring project? Could the participant survey be made more complete to include information on health? Could participants attach their own medical records to provide the researchers with more information?*

It is true that if the purpose of the pilot project were to examine potential links between health and PFC exposure researchers would need to gather health information from the participants. However, the goal of the biomonitoring pilot project is to determine the range of exposures to PFCs in the two communities sampled. Once this information is gathered, recommendations will be made for additional types of research, which could include a health study. Such health studies are more complex and time-consuming, while the scope of the PFC pilot project is more narrow – and shorter in duration – in order to meet deadlines set in the law.
Once the biomonitoring pilot project is done will it spur on other research? Will more studies be conducted?
Once the pilot project is completed, MDH will make recommendations to the legislature for what additional research might be needed. This could include more in-depth surveys of exposure, an expansion of biomonitoring to other groups in the community (e.g., children), follow-up testing to measure changes in exposure over time, or studies to learn more about the health effects of being exposed to PFCs.

What is the point of doing this project? Don’t we already know that Minnesotans have the highest levels of PFCs compared to the rest of the country?
The biomonitoring pilot project will help us learn how the PFC exposure levels of people in the selected communities compare to people in the rest of the country. Unless this testing is done, we may suspect that exposures are higher for people in Washington County, but we don’t know for sure whether there’s a difference or how big that difference is.

Will a correlation between miscarriage and PFC exposure be studied?
No. Examining the relationship between birth outcomes and PFC exposure is beyond the scope of the pilot project. Once the pilot project is completed, MDH will make recommendations for conducting additional types of studies in the future.

How long will this project go on? Will it be one time only? Won’t you have to test again to learn anything?
The pilot project involves a one-time measurement of participants’ PFC levels. The project will help us learn what levels of PFCs people have in their bodies. At the end of the pilot project, MDH will make recommendations about future areas of study that may be needed. One potential recommendation could be to repeat the testing in the future to determine whether PFC levels are falling.

Can MDH get access to 3M employees’ medical records in order to learn about health effects of exposure to PFCs?
Data privacy laws prevent MDH from obtaining anyone’s private medical records without their explicit permission. 3M scientists have published several reports of health studies among their employees exposed to PFCs. These reports are available to MDH and the public.

Can MDH estimate people’s past exposure? Can MDH go back and calculate what people’s PFC levels used to be?
Calculating past exposure and PFC levels can be done, but it is very complicated and is beyond the scope of the pilot project. At the end of the pilot project, MDH will make recommendations about future areas of study that may be needed.
**Participant eligibility**

In order to be eligible to participate, participants must live in one of the two selected communities. The first community is people who are currently living in residences served by the Oakdale municipal water supply. The second community is households in Lake Elmo and Cottage Grove who have or had private wells contaminated with PFOA and/or PFOS above trace levels. In addition, participants must be aged 20 or over and they must have been living at their current residence since before January 1, 2005.

*What does “above trace level” of PFOA and PFOS in the water mean?*

“Above trace level” means that PFOA or PFOS was detected in the water at more than 0.1 parts per billion.

*Will weight be given to those who have lived in the selected communities longer? Why isn’t some length of residence a criterion for participation? Can MDH compare results along length of residence? If there was a drastic difference between length of residence and concentration of PFCs in the blood would there be a follow-up?*

In order to be eligible, participants must have lived in their residence since before January 1, 2005. This ensures that everyone included in the project will have been exposed to the PFCs in the water. Other than that, weight will not be given to those who have lived in the community the longest. The goal of the biomonitoring project is to determine the range of exposures in the community as a whole, including people who have lived there for both long and short amounts of time. If the project focused heavily or exclusively on long-time residents, the results would no longer represent the whole community. Learning the range of exposures in the community as a whole is necessary for planning future biomonitoring studies. In addition, by including people with different lengths of residency, MDH may be able to analyze the results to determine whether there are differences in PFC levels based on how long someone has lived in the community. At the end of the pilot project, MDH will make recommendations about areas for future research.

*Why are children not included in the biomonitoring project?*

MDH agrees that children are an important population to be studied. Conducting the pilot project will provide MDH with the information necessary to be able to make recommendations for including children in future biomonitoring efforts. There are a number of reasons why children are not included in the pilot project.

Research involving humans – and children in particular – is carefully scrutinized by MDH’s Institutional Review Board to ensure that participants are treated in an ethical manner. A blood draw is an invasive medical procedure, and one that is more likely to cause bruising, bleeding and/or pain in children than in adults. It would be difficult to justify subjecting children to these risks when there are no potential health benefits that children would receive in return. In addition, there are currently no appropriate national values to which children’s results could be compared. There has been one study conducted to measure U.S. children’s PFC levels (using blood that was already collected for other purposes), but the blood samples were collected
too long ago to be a valid comparison and it is unclear whether the children included are representative of the general population.

In order to make decisions about designing studies that would include children, MDH must first determine the variability in PFC levels in the community as a whole, which the pilot project will accomplish. MDH is committed to exploring ways that children could ethically be included in future research projects. For example, one way to include children in future testing would be to combine testing for PFCs with some other medical test (one that could provide demonstrable benefit to the participants). However, this is beyond the scope of the pilot project.

Are there existing data for children from other sources (regional, national, international) to which east metro child data could be compared if collected? Will any such data be available in the near future?

There are few studies that have reported PFC levels for children. One U.S. study\(^1\) measured PFCs in stored blood samples of children from 23 different states. Because the data were collected over 10 years ago and because the levels of PFCs in the general population have been declining, this value is likely to be significantly elevated compared to children’s true levels today. To ensure a valid comparison, we will want to choose reference data collected in a year that is as close as possible to the sampling year of our project.

Other articles have reported PFC levels in children in Australia\(^2\) and a preliminary reference value for children in Germany\(^3\). While international values provide an interesting contrast to values found in the U.S., they do not provide a reliable reference value for the biomonitoring pilot project.

A fourth study\(^4\) measured PFC levels in children in Ohio and West Virginia, where the water was contaminated with PFOA. However, the authors did not publish the specific values that were measured in children.

The Centers for Disease Control and Prevention plans to publish national reference values for children ages 3-11 based on pooled blood samples (blood combined from stored samples from multiple children) in 2008 or 2009, which will facilitate the interpretation of Minnesota children’s results in any future research projects.

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Could MDH learn anything by just including a couple of kids in the project, even if a reference value doesn’t exist?

In order to obtain data that are statistically valid, a large number of children would need to be included in the project. If we were to include just a few children, we could not be confident that their data are reflective of children within the community in general.

Shouldn’t it be the parent’s decision whether or not to enroll their child in the study?

Research at MDH must be approved by an Institutional Review Board, so this is not simply an issue that can be left to parents to decide. The Institutional Review Board exists to ensure that the rights of research participants are protected and that participants are treated in an ethical way.

Why does the project not focus on pregnant women?

MDH recognizes that many community members are concerned about how PFCs might affect a developing fetus, and that this is an important area for future research. For the pilot project, it is not feasible to recruit 100 pregnant women from the selected communities within the timeframe available for completing the project. While the project does not explicitly focus on testing pregnant women, pregnant women will be eligible to participate. In addition, the sample will include women of child-bearing years. Results from these women will serve as an indicator of the levels of PFCs that a fetus would be exposed to in utero, and may be compared to similar findings in the U.S. population.

Why does the project not focus on the Hmong or Latino populations, who may be more at risk for PFC exposure?

Some research has shown that people from certain ethnic groups may have elevated levels of PFCs in their bodies, perhaps due to the consumption of certain types of fish. Unfortunately, the pilot project is not able to focus on all of the groups that could potentially be exposed to PFCs. Once the pilot project is concluded, MDH will make recommendations for additional areas of study, which may include biomonitoring in other groups than the ones included in the pilot.

For people with private wells, will only people who have had their wells tested be eligible to participate?

Yes. In order to participate in the pilot project, people who have private wells must have a documented well sampling result showing contamination with PFOA or PFOS in addition to PFBA. MDH’s private well sampling was conducted to identify wells that were very likely to be contaminated. Because of the methodical approach that was used for testing private wells, people who were not contacted to have their wells tested are considered very unlikely to have PFOA or PFOS contamination in their water.

In Oakdale, will preference be given to those who live closest to the contaminated wells?

No. The purpose of this project is to measure the range of exposure in the whole community. This would include people living close to the wells and those farther away. The Oakdale
community water system delivers water to a broad area of the community; living near the wells does not necessarily increase the likelihood that residents have more exposure to PFCs.

**Why does the project not focus on people with known health problems?**
The goal of the project is to determine the range of exposures in the community as a whole. Even if the project were to focus only on people with health problems we would not be able to determine whether those health conditions were caused by the PFCs or not.

**Will people be excluded from the project based on their health status?**
No.

**Sample selection/sample size**
Participants will be invited to be a part of the project through a specific recruitment process. First, all of the eligible households in each community will be identified (through well sampling records and city utility billing records). Then, some of the eligible households will be contacted with a brief survey to determine how many eligible adults live at each address. MDH will compile a list of eligible adults from the returned surveys and then 100 adults will be randomly selected from the list and invited to participate.

**Will all households in Oakdale, Lake Elmo & Cottage Grove be contacted with a survey?**
No. In Lake Elmo and Cottage Grove, all households that are or were served by private wells contaminated with PFOA or PFOS in addition to PFBA (this is estimated to be about 150 households) will be contacted and asked to complete a brief survey. In Oakdale, a sample of 500 households will be contacted.

**Will the list of 500 households that will be contacted in Oakdale include people who were previously on well water before being hooked up to municipal water?**
The 500 people will be randomly drawn from the list of all households that are currently being served by the Oakdale water supply, regardless of their previous water sources.

**How was the number 100 chosen as the sample size?**
The legislation that established the Environmental Health Tracking & Biomonitoring program specifies that the pilot project should collect specimens from 100 participants from each of two communities likely to have been exposed to PFCs. Having data on the PFC levels of 100 people in each of the two communities will provide a statistically valid estimate of the range of exposures in each community and is a good starting point for data collection.
If MDH is selecting 100 people out of 150 households served by contaminated private wells, and 100 people out of 9000 households served by the Oakdale municipal water supply, won’t there be an over-selection in the Lake Elmo and Cottage Grove communities and an under-selection in Oakdale?

While it is true that people served by contaminated private wells will have a higher likelihood of being selected for the biomonitoring project than people served by the Oakdale water supply, this does not mean that there will be over- or under-selection. The two communities will be treated as two distinct groups. The results from the two groups will not be combined. Instead, there will be information on one population with well water consumption and one with municipal water consumption. A sample size of 100 people in each of the two communities will provide a statistically valid estimate of the range of exposures in each community.

Is it statistically valid to sample just 100 people out of 9000 households?
The size of the sample needed in order to draw conclusions about community members’ exposure to PFCs depends on many factors, including the variability in the levels of PFCs detected in the participants and what level of accuracy researchers are hoping to attain. As long as random sampling methods are used, the size of the overall population actually has relatively little impact on the sample size needed, except when the overall population is very small. A sample size of 100 people in each of the two communities will provide a statistically valid estimate of the range of exposures in each community and is a good starting point for data collection.

Will participants truly be randomly selected? Will MDH stratify the sample based on age?
MDH will be using a simple random sampling procedure to select participants, which means that 100 participants will be randomly selected from the list of eligible adults that is compiled in each of the two communities. This process should lead to a sample that is representative of the community as a whole (e.g., based on gender, age, and other factors). However, some age groups may be under-represented in the sample because some groups may be more likely to respond to the invitation to participate than other groups. Stratified random sampling, which would ensure representation in every defined age category, is beyond the scope of this pilot project.

What will MDH do about participants who die, move away, etc? Shouldn’t MDH recruit more than 100 people to address the possibility that some of the participants won’t be able to complete the project?
The biomonitoring pilot project is not a longitudinal study, which means we will not be following the participants over time. The project involves a one-time collection of a blood sample, so right now only 100 people will be recruited.

Will MDH be asking for volunteers to participate in the testing?
No. Participants will be invited to participate in the biomonitoring project based on specific selection criteria. Once invited to participate in the project, the decision to participate is up to the individual. In that sense, participation in the project is voluntary.
**Does MDH have a statistician involved on this project?**
Yes. We have a statistician on our staff and also an external science advisory panel guiding our project.

**Measuring PFCs in the body**
In order to measure PFCs, participants must provide a blood sample. Blood is used (as opposed to urine or some other body fluid or tissue) because PFCs are known to circulate in the blood while they are in the body. Participants will be referred to a clinic or hospital in the project area in order to have the blood sample drawn.

**What PFCs will the project measure?**
Participants’ blood will be analyzed to determine the levels of PFOA, PFOS and PFBA in their blood. These are the 3 most common PFCs that have been detected in the water in Washington County.

**How many blood samples will be taken from the individual?**
Each participant will be asked to provide one blood sample, consisting of about 20 cc’s of blood.

**Where will the blood samples be analyzed?**
The Public Health Laboratory at MDH will conduct the laboratory analysis for the biomonitoring pilot project. The Public Health Laboratory will work closely with the Centers for Disease Control and Prevention to ensure that testing in Minnesota will be done in the same way as for the national sample. The MDH Public Health Laboratory has extensive experience and qualifications to analyze for PFCs.

**Communicating project results**
MDH will communicate the results from the biomonitoring projects in a number of ways. Individual participants will receive their own results along with some information about how their individual result compares to the national average. Summarized results of the project will be shared with community members through articles in local newspapers, the Internet, presentations at community meetings, and other methods as appropriate.

**Will MDH let individual participants know their results? Will MDH just list participants’ results or will MDH provide some analysis?**
Each participant will be provided with their own result along with information explaining how that result compares to the national average.
If people in the community test higher for PFCs than the comparison value (NHANES), will there be negative repercussions for our community?
MDH does not know of specific community-wide repercussions associated with the possibility of detecting elevated levels of PFCs in people’s blood. Some residents have expressed concerns that their housing values might decline based on publicity about the water contamination. Finding that people in the community test higher for PFCs may increase the likelihood of future studies taking place in the community.

Will the data from Cottage Grove and Lake Elmo be grouped or will MDH be able to separate it?
The data collected from Cottage Grove and Lake Elmo participants will be grouped together. The number of wells in Cottage Grove that are contaminated with PFOA or PFOS in addition to PFBA is very small (about 30), and not all of these households will be selected to participate in the project. With such a small number of households, it would be difficult to provide a meaningful interpretation of the data.

When will the results be available?
Blood samples will be drawn and analyzed during the summer of 2008. Individuals will receive their results within three months of having their blood drawn. Grouped data will be available by early 2009.

Data privacy
All individual data collected for the biomonitoring pilot project is classified as private. This means that MDH is not allowed to release data that would identify an individual participant. The only information that will be shared with the public is summarized data.

Will these records be made public? Could my health provider find out? Will we MDH be sharing the study information with insurance companies?
Individual results will only be released to the individual participants. MDH will not share individual results with anyone else, including participants’ physicians or insurance companies. Only summarized data will be released to the public.

After the project ends, who gets the data? Where does it go?
The data are stored in a secure location at the Minnesota Department of Health. MDH protects private, non-public data; this means that individuals’ results are safeguarded.
Project logistics

*Why is this project so delayed in getting started? It’s been a long time since filters were put in place [in Oakdale], so MDH will be less likely to find PFCs in people’s blood. Why does the study take so long to conduct? Why does it take so long for results to become available?*

The funding for this project stems from legislation that went into effect on July 1, 2007, so MDH staff could not formally begin work on the project until then. Planning a scientifically valid project takes considerable time, and the project proposal must be approved by a science advisory panel and the MDH Institutional Review Board before the project can be implemented. Once the project receives final approval (probably in April or May) participant recruitment and sample collection will begin. Although most eligible participants have been using filtered or alternative water sources, due to the long half life of PFOA and PFOS, these chemicals will still be detectable in people’s bodies.

*How much money was allocated to the biomonitoring program? Why is it costing MDH so much money to test 200 people?*

Approximately $300,000 is allocated to biomonitoring per year for two years, for a total of $600,000. Of this total amount, approximately $370,000 is dedicated to the PFC biomonitoring pilot project. This money pays for the costs of collecting blood samples at a clinic, costs of laboratory analysis, and staff salaries, supplies and expenses necessary for implementing the project (e.g., designing the project protocol, recruiting participants, analyzing data, reporting results to participants, etc.).

*Where did the money for the biomonitoring project come from? Shouldn’t 3M pay for it?*

Funding for the project came from the state legislature. MDH does not have the authority to compel 3M to pay for conducting the project, nor is 3M obligated to pay these costs.

Health effects of PFCs

*How serious is exposure to PFCs? How elevated a PFC measurement does one need to have in order to have ill health effects? Are there results from any other studies that give us a clue about the health effects of PFCs?*

So far there has not been a lot of research on the human health effects of exposure to PFCs, including the health effects associated with specific levels of exposure to PFCs. There is currently very little information available on the health effects of PFCs in the general population, although a study of 70,000 people exposed to PFOA in drinking water in Ohio and West Virginia is underway. Studies by 3M of workers exposed to PFCs during manufacturing show no apparent impact on their health. Unfortunately, it can take many years to determine whether there are links between exposure to a particular chemical and human health.
If no one knows what level of PFCs in the body are related to health effects, then why is the biomonitoring project being done? While biomonitoring does not provide the same information as a health study would it does provide information on current levels and variability of PFCs in people’s bodies. Having this information will inform the design of future biomonitoring studies in the community. For example, knowing this information will help researchers determine what sample size would be needed to be able to make comparisons between different sub-groups in the population. In addition, having information on the current levels of PFCs would also be useful as a comparison if PFCs are measured again in the future to determine whether PFC levels are declining over time. If we don’t see a decline over time this would suggest that there is another significant route of exposure that needs to be considered. The biomonitoring project is a pilot study, meaning that MDH will be testing how the state health department might conduct biomonitoring on a larger scale and over a longer time frame in the future.

Are there other communities in the United States where research on PFCs is happening? Yes. As a result of a large legal settlement with DuPont several studies are underway in Ohio and West Virginia, where residents were exposed to PFOA in the drinking water. These studies include testing for PFOA in people’s bodies and an examination of the health effects associated with exposure to PFOA. The studies will be based on biomonitoring and health data gathered from nearly 70,000 residents. In addition, some residents will be followed over a period of four years to track new health conditions they develop. The studies will attempt to determine whether there are links between PFOA exposure and cancer, birth outcomes, cardiovascular disease, and liver, hormone and immune system disorders. Funding for the community health studies was provided by DuPont as a result of a class-action lawsuit settlement. For more information about this project, go to http://www.c8sciencepanel.org/ and/or http://www.hsc.wvu.edu/som/cmed/c8/. Results will be posted at these websites as they become available. Some results will be available in 2008, while other results will not be available until 2011.

My understanding is that even though the levels of PFCs in the treated water in Oakdale are minimal, because PFCs have a long half-life, the concentrations of PFCs in people’s blood will continue to rise if they drink the water. Is it true that the PFCs may never leave your body? The rates at which PFCs accumulate and leave the body are not very well understood. Some PFCs, such as PFOA and PFOS may take up to 20-30 years to leave the body. As exposure to PFCs decreases, however, we would expect the levels of PFCs in the body to decrease as well. We know that people all across the country have PFCs in their bodies, even those who are not exposed through drinking water, so it is likely that most people will continue to have some amount of PFCs in their bodies long after exposure through the water is reduced or eliminated. Examining the rate at which PFC levels decline in people’s bodies is one potential area for future research.
Other questions
What is the national average for PFC levels? Who collects this information? How often do they measure it?
Based on the most recent data reported (2003-2004), the national average for PFOA is 5 parts per billion and the national average for PFOS is 25 parts per billion. The national survey does not collect information on PFBA, so no national average exists for PFBA. This information is collected by the Centers for Disease Control and Prevention (CDC), as part of the National Health and Nutrition Examination Survey (NHANES). Biomonitoring results from this project are reported every two years in the publication *National Report on Human Exposure to Environmental Chemicals*. This report, along with additional results published since the report was released, is available online at [www.cdc.gov/exposurereport](http://www.cdc.gov/exposurereport).

Has any thought been given to conducting PFC biomonitoring (or some other kind of research) in pets? Can these chemicals affect animals? Many of my pets have died of cancer.
The legislation that funds the PFC biomonitoring project specifies that the samples must be collected from humans. MDH understands that residents are concerned about their pets, and, in fact, research on pets can be very instructive for learning about exposures to chemicals in the environment. At this time, however, there is no funding for such a project. Residents who would like to know more about why their pets have died could contact their veterinarian to arrange an autopsy.

If someone wanted to participate and was not chosen as a volunteer where might they seek testing independently of the study? Will insurance cover the costs of testing? Will MDH educate physicians in the area so they are made aware that a PFC test exists?
At present there are very few laboratories in the country that can reliably measure PFCs in the blood. MDH is currently investigating which labs are able to conduct this analysis for private citizens and are also looking into the feasibility of making arrangements with a clinic in the community to be a central location for residents who wish to be tested. Some insurance companies may pay for this test, though some residents may prefer to have the test performed without their insurance company’s knowledge. The likely cost for the laboratory analysis is about $600, not including fees that a clinic might charge for drawing and shipping the blood. MDH plans to reach out to physicians in the area so they are aware of the biomonitoring project and have access to PFC-related educational materials.

What are the risks of participating in the project?
The risks of participating in the project are relatively few. Because participation requires a blood draw, there is a risk of pain and bruising. In addition, some participants might become anxious after learning about the levels of PFCs in their bodies.
How can residents provide input back to the study planners?
Community members can provide input to the biomonitoring project staff by emailing or calling Michonne Bertrand (michonne.bertrand@health.state.mn.us or 651-201-3661).

Will information about the biomonitoring project be available online?
Information about all of the biomonitoring pilot projects is available on the MDH website at http://www.health.state.mn.us/divs/eh/tracking/biomonitoringpilot.htm. Additional information will be added as it becomes available.

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