

Perfluorinated Compound Biological Sampling in the Vicinity of Morgan, Lawrence, and Limestone Counties, Alabama

ATSDR Exposure Investigations (EI) Generic Information Collection Request
OMB No. 0923-0048
Expiration Date: 05/31/2016

Attachment 1: Supporting Statement Part A

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ATTACHMENTS

- 1. Supporting Statement A**
- 2. Supporting Statement B**
- 3. Decatur EI Assent/Consent/Parental Permission Forms**
 - a. Adult Consent Form (≥ 18 years of age)**
 - b. Adult Consent Form for Sample Storage (≥ 18 years of age)**
 - c. Assent Form for Children (12 - < 18 Years)**
 - d. Assent Form for Children for Sample Storage (12 - < 18 Years)**
 - e. Parental Permission Form for Children (12 - < 18 Years) Participating in Investigation**
 - f. Parental Permission Form for Sample Storage for Children (12 - < 18 Years) Participating in Investigation**
- 4. Decatur EI Questionnaire**
- 5. Decatur EI Human Subjects Research Determination Form**
- 6. Decatur EI Sample Results Letters**
- 7. Example of Prior Exposure Investigation Final Report**

- **Goal of the Study:** This project has four primary objectives:
 - Compare concentrations of perfluorinated compounds (PFCs) measured in each individual with their past PFC concentrations measured during the 2010 EI.
 - Compare individuals' serum PFC concentrations to the national reference population (NHANES 2011-2012).
 - Calculate the biological half-life for each PFC species using paired blood and urine PFC concentrations to improve the understanding of the pharmacokinetic behavior of these compounds in humans in this community.
 - Evaluate the potential existence of non-drinking water PFC exposure pathways through physiologically-based pharmacokinetic (PBPK) modeling.
- **Intended Use of the Resulting Data:** Data will be used to provide information to the community about their ongoing and past exposures to PFCs, to inform public health recommendations and evaluate the success of past mitigation activities, and to contribute to the scientific body of knowledge concerning human exposures to PFCs in this community. PBPK modeling will be used to interpret individual results in the context of exposure and will help ATSDR scientists to evaluate the potential existence of non-drinking water exposure pathways. The results of this EI are not intended to be generalized and are applicable only to the sampled participants
- **Methods to be Used to Collect:** Samples will be collected from members of the community who participated in a past exposure investigation. This EI aims to evaluate changes in PFC-serum concentrations and thus, participant selection is specifically biased to residents who participated in the 2010 EI, rather than statistical random selection methods used in research to generate or contribute to generalizable knowledge.
- **Subpopulation to be Studied:** Adults and children over the age of twelve living in Morgan, Lawrence, or Limestone Counties, Alabama. Subpopulation to be study will be the members of the community who participated in the 2010 EI, although additional participants will be included if fewer than 75 past EI participants are willing to participate.
- **How Data will be Analyzed:** Each individual's measured PFC-serum concentrations will be compared to their own past PFC-serum concentrations measured in the 2010 EI. Arithmetic and geometric mean PFC-serum concentrations will be compared to national reference populations (NHANES). Paired blood and urine concentrations will be used to calculate biological half-life for each PFC species in each individual; these calculated values will be compared to reports of biological half-life available in the literature and will be used to parameterize a human PBPK model for select PFC species. This PBPK model will be used to explore the possibility of non-drinking water pathways of exposure in this community.

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

This data collection is being conducted using the Generic Information Collection mechanism of the Agency for Toxic Substances and Disease Registry (ATSDR) Exposure Investigations (EIs) (OMB No. 0923-0048, expiration date 5/31/2016). The data collection for the Decatur Exposure Investigation (EI) aligns with the agency's mission.

The data collection is authorized by the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the "Superfund" Act, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986.

ATSDR Public Health Assessment Process and the Role of the Exposure Investigation

In May 2007, a PFC manufacturer in Decatur, Alabama, notified the U.S. Environmental Protection Agency (EPA) that it had unknowingly discharged large amounts of perfluorocarboxylic acids (PFCA) into the Decatur Utilities' Dry Creek Wastewater Treatment Plant. PFCA is a class of PFCs that includes perfluorooctanoic acid (PFOA) and other PFCs. PFCs are a class of organofluorine compounds that are used in a variety of industrial and consumer products, including fire-fighting foams; personal care and cleaning products; and oil, stain, grease, and water repellent coatings on carpet, textiles, leather, "non-stick" cookware and paper such as wrappers used on fast food items. As a result, the general United States (U.S.) population's exposure to PFCs is common.

From 1996 to 2008 treated sewage sludge (biosolids) from Decatur Utilities was used as a soil amendment on about 5,000 acres of privately owned agricultural fields in Lawrence, Morgan and Limestone Counties, Alabama. In September 2007, EPA screened biosolids and soil for PFCs in a small number of these agricultural fields. PFCs were elevated compared to background levels. In February and March of 2009, EPA followed up with additional sample collection of the surface water, ground water, drinking water, and soils in the area around the treated fields to determine the concentrations of PFCs and PFC precursors. EPA found PFC chemicals in the Decatur Utilities' biosolids, in soils, surface water, ground water, and drinking water.

In 2009, EPA requested that ATSDR conduct an EI to address potential exposure by residents living near Decatur, AL. PFCs were detected in many environmental media in the community and, at this time, it was unclear how and to what extent community members were exposed to these compounds. In 2010 serum samples from 155 residents of the Decatur area were collected and analyzed for 12 PFC species. In 2013, ATSDR released an EI report that detailed the results and identified drinking water from the West Morgan/East Lawrence public water system as well as contaminated private wells as a significant source of PFC exposure.

The results from the 2013 Decatur EI report indicated that geometric mean levels for three PFCs (including PFOA and PFOS) were elevated (about two to four times) in participants compared to the U.S. general population, but were similar to or lower than levels found in other U.S. communities exposed to PFCs via drinking water or other environmental pathways. The conclusions of the 2013 Decatur EI report recommended continued monitoring for PFCs in the affected public water supply and other potentially impacted public water supplies downstream of Decatur, Alabama as well as follow-up biological PFC testing in this community in order to determine if exposure to PFCs in this community has been reduced.

An additional EI that includes biological sampling for 12 PFC species in serum and urine is proposed for the Decatur site.

The Exposure Investigation Criteria and Recommendation Process

Four criteria must be met for the EI to be approved and conducted. The criteria are:

1. Can an exposed population be identified?
2. Does a data gap exist that affects the ability to determine if a health hazard exists?
3. Can an EI be designed that will address this data gap?
4. Will the EI results impact the public health decision for the site?

If the answers to these questions indicate that an EI would allow ATSDR to make a better-informed public health call, the DCHI EI Team may conduct agency-led EIs. For the Decatur site, the responses to the four questions (provided below) indicated that an EI is warranted at the site.

The EI Team from the DCHI Science Support Branch (SSB) and ATSDR Region 4 will lead the investigation, evaluate the results, and communicate their public health findings and recommendations to the community (further discussed in Section A.2).

Decatur Exposure Investigation

The four questions used to establish whether it was appropriate to conduct a follow-up EI for the Decatur site were as follows:

1. *Can an exposed population be identified?*

Yes. PFCs have been detected in the soil, surface water, and ground water in the vicinity of Lawrence, Morgan, and Limestone Counties, Alabama as well as in the drinking water supply provided by the West Morgan/East Lawrence Water Authority and in private drinking water wells in the area. Further, PFCs were detected in serum samples from 153 participants that live in the Decatur, Alabama community, suggesting that this population has been exposed to PFCs.

2. *Does a data gap affect our ability to decide whether a public health hazard exists?*

Yes. Additional biological sampling is necessary to determine if exposure to PFCs is still occurring in this community, and whether mitigation activities (e.g. improved filtration of public water supply, providing an alternative water source to residents with contaminated private wells, educational outreach, etc...) have been effective at reducing exposures. The currently available data gives us no information about ongoing exposure following efforts to reduce exposure.

3. *Can an EI address the data gap?*

Yes. A second exposure investigation will give ATSDR the data necessary to determine if serum PFC concentrations in this community are declining and will identify whether additional public health actions are needed. Additional biological sampling will allow ATSDR to evaluate changes in serum PFC concentrations over time. This data will also allow ATSDR to more fully characterize non-drinking water exposure pathways in this community using PBPK modeling.

4. *How will the EI results impact public health decision making?*

Additional sampling will provide community members, the Alabama Department of Environmental Management, and the EPA with additional information about PFC body burden in this community. This will allow for evaluation of the efficacy of mitigation activities that have been implemented following ATSDR's first exposure investigation. Further, this data will allow ATSDR to more fully characterize ongoing exposures from multiple pathways and will inform public health decisions regarding future mitigation activities.

The results of this EI are not intended to be generalized and are applicable only to the sampled participants. However, this exposure investigation will result in sufficient data (paired serum and urine concentrations for each PFC) for physiologically-based pharmacokinetic (PBPK) modeling of PFC exposure in order to better understand the toxicokinetics of PFCs in human bodies – an area of great scientific uncertainty. This advancement of science will allow the public health community to better understand the human toxicology of exposure to these compounds, thus allowing them to make more informed public health decisions. PBPK modeling will also allow ATSDR scientists to interpret each individual's biomonitoring data in the context of exposure and to evaluate the potential existence of non-drinking water exposure pathways.

Once the EI data collection and analysis is complete, if indicated, ATSDR will make recommendations, as needed, for exposure reduction to the EPA and appropriate state and local agencies. These recommendations will also be provided to the community during a public availability session.

Once all samples and data have been collected and analyzed, a full EI Final Report will be completed and made available to the public and all partners. An example of a past EI Final Report is included as Attachment 7.

A.2. Purpose and Use of Information Collection

The goal of the EI is to determine whether PFC contamination in environmental media is resulting in community members continuing to be exposed to PFCs at levels of health concern. ATSDR found levels of concern in the 2010 EI and this second EI will evaluate whether exposure is continuing in the community. If this is the case, ATSDR will make recommendations people can take to reduce their exposures and will recommend contaminant mitigation to the appropriate government agencies [e.g., the U.S. Environmental Protection Agency (EPA) and their state equivalent]. If exposures are found at levels that might cause health concerns, ATSDR may recommend the following:

1. Expanded implementation of improved filtration on the public water system.
2. Expanded sampling to further characterize non-drinking water exposure pathways, and
3. Increased educational outreach.

Data from ATSDR's Decatur EI report may also be used by public health professionals, environmental risk managers, and other decision makers in determining the extent of the exposures.

ATSDR will produce this needed information to support public health action. The results of this EI are not intended to be generalized and are applicable only to the sampled participants.

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. Once we conduct an EI, we match the unique answers given by participants with their laboratory results or environmental samples to determine whether intervention is needed on an individual level. The information collection is therefore *inherently person- or location-specific*.

Data are treated to protect privacy; access to computer files is password-protected and access is limited to authorized EI personnel, including contractors. All staff working on the project agree to safeguard the data and not to make unauthorized disclosures. Published reports may present responses in aggregate form and no individuals are identified by name.

A.3. Use of Improved Information Technology and Burden Reduction

ATSDR will conduct computer-assisted personal interviews (CAPIs) with the participants at the blood collection location. The results of the interview will be recorded on paper questionnaire forms in the field and then entered into Epi-Info, an NCEH/ATSDR information system that enables scientists and epidemiologists to collect and analyze questionnaire data.

A.4. Efforts to Identify Duplication and Use of Similar Information

This second EI is intended to fill data gaps identified from the original EI that ATSDR completed at the site in 2010.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses are included in the Decatur EI.

A.6. Consequences of Collecting the Information Less Frequently

This request is for a one time data collection. There are no legal obstacles to reduce the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this data collection. The data collection will fully comply with the guidelines of 5 CFR 1320.5 and will be voluntary.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This data collection is being conducted using the Generic Information Collection mechanism for Exposure Investigations – OMB No. 0923-0048 (expiration date: 05/31/2016). A 60-day Federal Register Notice was published in the Federal Register, Vol. 77, No. 61 on Thursday, March 29, 2012. No comments were received.

A.9. Explanation of Any Payment or Gift to Respondents

ATSDR will not provide payments or gifts to participants.

A.10. Assurance of Privacy Provided to Respondents

This submission has been reviewed by CIO who determined that the Privacy Act does apply. The relevant Privacy Act System of Records Notice (SORN) for this EI is the Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances (HHS/ATSDR) (SORN 09-19-0001, Volume 53, Page Number 30702, Publication Date 08/15/1988). This SORN is intended to allow for the implementation of the legislated mandate of ATSDR to identify the public health threat caused by exposure to toxic and hazardous substances using exposure investigations.

Data obtained during the exposure investigation will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Alabama's Sunshine laws were replaced by the Alabama Open Meetings Act in 2005. This legislation does not provide access to personal identifying information.

Institutional Review Board

Federal Regulations for Protection of Human Subjects (45 CFR 46) state that "research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." In contrast, this EI is intended to be a systematic investigation but is not designed to develop or contribute to generalizable knowledge. This EI is a nonresearch activity and human subjects review by an Institutional Review Board

(IRB) is not required. The EI was reviewed by the NCEH/ATSDR Human Subjects Coordinator who is designated to make human subjects research-or-non-research determinations on a case-by-case basis (Attachment 5). A.10.1. Privacy Impact Assessment Information

The Decatur EI will involve up to 155 participants, including children age 12 and older, pregnant women, and women of child-bearing age. ATSDR provides participants with information on the EI process and what it can and cannot determine. After providing the participants this information, ATSDR will ask for parental permission and minor assent, or adult consent to participate in the EI. Participation is completely voluntary; participants can stop participating in the EI at any time.

Overview of the Data Collection System

The primary objective of the information collected for the Decatur EI is to assess exposures to PFCs in biological samples (e.g., serum and urine). Information obtained from the participants assists the team in determining if exposure has occurred or is occurring. For this EI, a data collection system will include all of the measurements and procedures that are proposed to address data gaps in the biological sampling at the site.

The data collection system for this EI will be characterized by the following:

1. Who will use the EI Data Collection System?

The DCHI SSB EI Team and the ATSDR Region 4 staff will use the Data Collection System to perform the biological collection and laboratory analysis during the Decatur EI.

2. Who can be included as part of the EI Generic Clearance?

EI participants for the Decatur EI are identified as the participants included in the previous 2010 EI and others recruited from Morgan, Lawrence, and Limestone counties.

Up to 155 participants will be recruited based on the following prioritization:

- First Priority Target Group: Participants in the 2010 EI who continue to live in Morgan, Lawrence and Limestone Counties.
- Second Priority Target Group: Participants in the 2010 EI who no longer live in Morgan, Lawrence and Limestone Counties.
- Additional participants will be recruited from Morgan, Lawrence, and Limestone Counties if fewer than 75 of the original 155 participants from the 2010 investigation are willing to participate.

ATSDR will target participants from the 2010 EI for recruitment into this investigation. ATSDR will contact all prior exposure investigation participants by phone to recruit them into the follow-up investigation. If telephone recruitment yields fewer than 75 participants, staff from ATSDR and local health agencies will hold a public meeting with the residents to attempt to recruit additional participants.

3. What types of questions may be asked as part of the EI Generic Clearance?

Attachment 4 provides the information collection form that will be used to evaluate chemical exposure of Decatur EI participants. Each participant will be asked a few questions to gather information on risk factors for exposure to PFCs through food pathways, contact with contaminated soil, or local well water use. Each participant will have their height, weight, and body fat percentage measured and recorded by an ATSDR staff person.

Items of Information to be Collected

Collecting identifying information is necessary to facilitate personal contact with participants, to obtain their assent/consent/parental permission to participate and to provide them with results. The information is also used by ATSDR to better interpret the results of the sampling. ATSDR uses the information only to contact respondents. Data is treated in a private manner, unless otherwise compelled by law.

ATSDR collects contact information (e.g., name, address, phone number, email address) to provide the participant with their individual results. Additional information to be collected for this EI include age, date of birth, height, weight and body fat percentage. Race, ethnicity and gender are also required to be collected. General information, which includes height, weight, age/date of birth, race, gender, etc., may also be collected primarily on biological investigations to assist with results interpretation.

ATSDR will ask participants in the area about their drinking water use and their intake of fish and locally grown produce. Only questions needed to determine the extent of exposure in a particular situation will be asked. The questions are intended to estimate how long and how frequently participants may have contact with PFCs in the environment. This information represents their individual exposure history.

The blood collection will be overseen by ATSDR personnel. Urine collection will take place at each individual's home (approximately 5 minutes). Each participant will attend two appointments. At the first appointment (approximately 15 minutes) the participant will sign consent forms, be given instructions and materials for urine collection, and have an opportunity to ask any questions. At the second appointment (approximately 15 minutes) the participant will submit their urine sample, have a blood sample collected, and complete a questionnaire. Blood samples will be obtained by trained phlebotomists and shipped directly to the Centers for Disease Control and Prevention (CDC) National Center for Environmental Health (NCEH) laboratory in Atlanta for analysis. Urine samples will be shipped directly to a contract laboratory for analysis. Appropriate Quality Assurance Plans will be prepared and implemented by ATSDR.

Sharing and Purpose of Collected Information

The information collected for the Exposure Investigation (EI) will be used to evaluate whether participants may have been exposed to PFCs in the environment in the area near Morgan, Lawrence, and Limestone Counties. Participants will be notified of their individual results and an EI report will be prepared that will present the results of the investigation.

Securing of Collected Information

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. Once we conduct an EI, we match the unique answers given by participants with their laboratory results to determine whether intervention is needed on an individual level. The information collection is therefore *inherently person- or location-specific*.

Data are treated to protect privacy; access to computer files is password-protected and access is limited to authorized EI personnel, including contractors. All staff working on the project agree to safeguard the data and not to make unauthorized disclosures. Published reports may present responses in aggregate form and no individuals are identified by name.

Data are treated in a private manner, unless otherwise compelled by law. Paper documents containing personal identifiers are kept in locked file cabinets at ATSDR. ATSDR computers comply with the HHS Standard 2008-0007.001S for encryption in accordance with information systems security requirements for safeguarding personally identifiable information. Access to computer files is password-protected and access is limited to authorized EI personnel. That information is stored in a secure database along with the laboratory and/or modeling results.

Applicability of the Privacy Act

A. The Privacy Act is applicable. The applicable System of Records Notice (SORN) is No. 09-19-0001, "Records of Persons Exposed or Potentially Exposed to Hazardous or Toxic Substances."

B. Identifying information such as name, address, phone number and email are collected. ATSDR uses the information only to contact respondents. Identifying information is necessary to facilitate the personal contact with respondents to conduct the questionnaire, to obtain consent to participate, and to provide them their results.

All identifying information maintained by the agency will be managed by ATSDR and is subject to the ATSDR Comprehensive Record Control Schedule (CRCS), B-371, which contains authorized disposition instructions for ATSDR's administrative and program records.

C. Respondent Consent –ATSDR will require that EI participants be fully informed of the potential risks and benefits of their participation and that the privacy of the participants' information will be protected. The parental permission, minor assent, and adult consent forms for the Decatur EI include all appropriate information from the Privacy Act including authority and purpose for collecting the data, with whom identifiable information will be shared, the voluntary nature of the information collection and the effect upon the respondent for not participating (Attachment 3). The EI will comply with all appropriate requirements.

D. Voluntary Nature - Respondents are told that their participation in the EI is voluntary and they may refuse to answer any of the questions.

A.11. Justification for Sensitive Questions

ATSDR will gather information about individual characteristics (e.g., gender, age, weight, ethnicity, and race) to assist with interpretation for biological samples. For example, the individual's laboratory results are compared to similar ethnicity and race results in the *National Report on Human Exposure to Environmental Chemicals* (<http://www.cdc.gov/exposurereport/>). Beyond that, questions of a sensitive nature will not be asked.

We will not ask questions on symptoms, medical outcomes, or drug and medication use. Social security numbers are not needed nor will be requested.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.1. Estimates of Annualized Burden Hours

The estimate for burden hours for the Decatur EI is based on similar EIs that the EI team has conducted in the past. The time burden per respondent is estimated at 35 minutes total – 5 minutes for urine collection, 15 minutes for the first appointment (to sign consent forms and receive urine collection materials), and 15 minutes for the second appointment (to submit the urine sample, give a blood sample, and complete a questionnaire). The questionnaire for this exposure investigation includes 18 questions that are expected to take less than 30 seconds each to respond. For purposes of estimation of burden hours, we are assuming that all 155 participants in the first EI will be willing to participate in the second EI. The total estimated burden hours are 93.

Estimated Annualized Burden Hours

Type of Respondents	Name of Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (In Hours)
EI participants	Participant Questionnaire	155	3	12/60	93

A.12.2. Annualized Cost to Respondents

Using a rate of \$22.33/hr., the annualized cost to respondents for the hour burdens for the collection of information is \$2077. The hourly wage rate is based on the U.S. Department of Labor, Bureau of Labor Statistics' most current statistics [May 2013 National Occupational Employment and Wage Estimates United States, released April 1, 2014].

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	No. Responses per Respondent	Hourly Wage Rate	Total Respondent
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				Costs
EI participants	93	3	\$22.33	\$2077

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the participants other than their time to participate in the EI.

A.14. Annualized Cost to the Government

Costs for ATSDR personnel are estimated based on experience with previous EI activities.

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Environmental Health Scientist (Lead – GS-13)	1000	\$43.70	\$43,700
Medical Officer (Medical Officer – O-6)	200	\$50	\$10,000
Estimated Total Personnel Cost of Exposure Investigation			\$53,700

Non-Personnel		
Travel costs		
Atlanta Personnel		\$5,000
Regional Personnel		\$0
Laboratory costs		
Includes phlebotomist, shipping and sample analysis		\$40,000
TOTAL NON-PERSONNEL COSTS		\$45,000
TOTAL EI COST	Personnel + Non-Personnel costs	\$98,700

The travel costs include the following:

- Travel to the site from Atlanta (2 people) for one week to perform the biological sampling
- Travel to the site from Atlanta (2 people) for 2-3 days for follow-up meetings

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

A.16.1 Project Time Schedule

The project Time Schedule for the Decatur EI is as follows:

Activity	Time Schedule
Start of data collection and field work	1 week after OMB approval
Data and laboratory analysis.....	2-3 months after OMB approval
Respond to participants	3-6 months after OMB approval
Written report.....	TBD - based on clearance process

Response letters to the participants will be sent for those with elevated and normal (Attachment 6) results. An example of a prior Exposure Investigation report is provided as Attachment 7.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not requesting an exemption.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification for Paperwork Reduction Act.