

SUPPORTING STATEMENT

QUESTIONNAIRE FOR DRINKING WATER UTILITIES PARTICIPATING IN  
EMERGING CONTAMINANT SAMPLING PROGRAM

INFORMATION COLLECTION REQUEST SUPPORTING

U.S. ENVIRONMENTAL PROTECTION AGENCY

SEPTEMBER 2009

## PART A OF THE SUPPORTING STATEMENT

### 1. IDENTIFICATION OF THE INFORMATION COLLECTION

#### 1(a) Title of the Information Collection

*Questionnaire for Drinking Water Utilities Participating In Emerging Contaminant Sampling Program (New)*

#### 1(b) Short Characterization/ Abstract

This Information Collection Request (ICR) package requests the Office of Management and Budget (OMB) to review and approve the U.S. Environmental Protection Agency's (EPA's) Office of Research and Development survey titled "Questionnaire For Drinking Water Utilities Participating In Emerging Contaminant Sampling Program".

Improvements in analytical chemistry instrumentation have allowed scientists to detect trace amounts of chemicals that are commonly used in homes in the environment. These so-called "emerging contaminants" are chemicals, such as pharmaceuticals, personal care products, detergents and even endogenous hormones, which are either excreted from or washed off the body, and enter the wastewater treatment system. Wastewater treatment is not designed to specifically remove these chemicals, so a portion of the chemicals remain in wastewater treatment plant (WWTP) effluents. WWTP effluents are commonly released into surface waters. Natural processes such as photolysis, sorption, volatilization, degradation, and simple dilution further attenuate the concentrations of emerging contaminants. However, if a Drinking Water Treatment Plant (DWTP) intake is located downstream of a WWTP effluent outfall, there is a potential for these chemicals to be present in finished drinking water.

The EPA's Office of Research and Development, in collaboration with the U.S. Geological Survey (USGS), is conducting a sampling program at up to 50 DWTPs to determine the presence of these emerging contaminants in both the source water and finished drinking water. To better interpret the results of the sampling program, detailed information concerning the operation of the DWTP at the time of sampling is required. This information can only be gathered through a questionnaire that is completed concurrent to the collection event. The questionnaire will collect information on the following:

- The population served by the DWTP;
- The source water, potential sources of pollution and current hydraulic conditions;
- Detailed treatment steps used by the DWTP, including parameters such as pumpage at sampling, disinfectants used, and distribution system information;
- Detailed water quality parameters at the time of sampling.

The DWTPs involved in this project will ship samples of their source water and finished water to the EPA and USGS laboratories. All sampling supplies and paid shipping vouchers will be provided to the DWTPs. The samples will be analyzed by the EPA and

USGS for a suite of approximately 200 emerging chemical and microbial contaminants. A detailed listing of the analytes, as well as the methods to be used can be found in public docket for this ICR under Docket ID No. EPA-HQ-ORD-2009-0114, which is available for online viewing at [www.regulations.gov](http://www.regulations.gov), or in person viewing at the Research and Development Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC.

This project is not designed to provide a statistical representation of the source and finished waters in the United States. The sampling is intentionally skewed to DWTPs that have known or strongly suspected sources of wastewater in their drinking water source water, in an attempt to determine the upper bounds of chemical detection frequency and concentration. This data can then be considered when designing future sampling events which are designed to be statistically representative of the DWTP population.

The EPA will distribute the questionnaire to the DWTPs at the time of sampling along with the sampling supplies. The EPA estimates the total respondent burdens and costs associated with completing the questionnaire are approximately 1000 hours and \$29,485. The cost estimate includes operational costs of photocopying and mailing the completed questionnaire to the EPA (\$250) if the DWTP chooses not to submit the form electronically. There are no capital costs associated with the survey. Additional details on burden can be found in Section 6. An overview of the burden is provided below:

- Estimated number of potential respondents: 50
- Frequency of response: One-time
- Estimated total number of responses for each respondent: One
- Estimated total annual burden hours: 1000
- Average burden hours per respondent: 20
- Average cost per respondent: \$589.70 (\$29,485)

## **2. NEED FOR AND USE OF THE INFORMATION COLLECTION**

### **2(a) Need/Authority for the Information Collection**

The Safe Drinking Water Act, as amended in 1996, authorizes the EPA to establish health-based standards limiting the concentration of natural and man-made contaminants in drinking water. The questionnaire that is being reviewed in this package supports a screening sampling project which will analyze drinking water samples collected across the United States for a suite of approximately 200 emerging contaminants. The results of this study will help the EPA's Office of Research and Development advise the EPA's Office of Water determine which chemicals (if any) should be considered for future regulation in drinking water.

### **2(b) Practical Utility/Users of the Data**

The EPA plans to use a survey questionnaire to solicit detailed information from DWTPs participating in an emerging contaminants sampling project. The EPA will use this information to help interpret the data collected during the water sampling program.

### **3. NON DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION EFFORTS**

#### **3(a) Non duplication**

The National Exposure Research Laboratory of the EPA's Office of Research and Development has made every reasonable attempt to ensure that the questionnaire does not request information available through less burdensome mechanisms. Many DWTPs maintain information on the treatment technologies in use in their utility on a website or in their annual consumer confidence reports (CCRs). However, there is no consistency between utilities on the detail of information available through these mechanisms. In addition, concerns over homeland security have caused some information (such as drinking water intake locations and their proximity to wastewater effluent outfalls) to be publically unavailable. The information gathered in the questionnaire will provide consistent information across all DWTPs studied in this project. There is some overlap between questions asked during the pre-questionnaire telephone survey and on the questionnaire itself. The telephone survey will be used to solicit participation in the study, as well as gather cursory information about each DWTP. The burden of the minimal repetition between the telephone survey and the questionnaire is outweighed by the value of having all pertinent information captured in the single questionnaire response.

#### **3(b) Public Notice Required Prior to ICR Submission to OMB**

##### **(i) Publication of the Federal Register Notice**

The EPA published a Federal Register notice (74 FR 15966) announcing the Agency's intent to submit a request for a new Information Collection Rule (ICR) to conduct a survey of drinking water utilities participating in a research project. In addition to the announcement, the Federal Register notice solicited comments to the draft questionnaire that will be given to participants. A copy of the notice is included in Attachment A.

##### **(ii) Public Response to Federal Register Notice**

The EPA received three comments on the initial Federal Register notice (FRN; 74 FR 15966). The FRN solicited comments as to the paperwork burden imposed on drinking water utilities participating in a future EPA/USGS sampling project as required by the Paperwork Reduction Act (PRA; 44 U.S.C. 3501 *et seq.*); all the of comments received included detailed remarks outside the scope and intent of the specific request addressing specifics details of the sampling project itself. While these comments are not germane to the PRA burden, we appreciate the constructive components of these remarks and address them in this response. All of the letters presented similar concerns, so the comments have been aggregated in this response. The comments are separated by commenter, and are visually set off from the responses by *italics*.

#### **Collective Comment 1: Scope, Format, and Use of Questionnaire**

**Commenter A.** AMWA is also concerned about the use of the study questionnaire responses together with paired source and finished water samples “to help interpret the data collected during the water sampling program.” The proposed questionnaire appears to be aimed at collecting information that could be used to draw conclusions about treatability as opposed to occurrence. AMWA believes that such conclusions would be inappropriate given the limited number of samples to be collected and the fact that only one paired sample (essentially two grab samples) will be collected.

**Commenter B.** Similarly, the information collection request encompasses data items like: population served, detailed description of the treatment provided, blending practices, and the number and types of upstream outfalls. The docket does not provide a rationale for why these data are being collected, nor does it suggest how this information might be of value to any existing or proposed regulatory program at EPA.

**Commenter C.** The Potomac Partnership’s Metro Utility Committee believes that the survey questionnaire is inadequate for interpreting the results of the sampling program for a number of reasons. Part B of the questionnaire asks for information on wastewater and industrial discharges within 25 miles upstream of an intake which seems to be an arbitrary distance. A better approach would be to define the area of interest for this information (watershed, time-of-travel, source water assessment area, etc.) or explain why a certain distance is significant.

The ICR announcement and questionnaire seem to emphasize wastewater treatment plants as the primary source of emerging contaminants although there are others sources of these compounds such as agribusinesses. While there is a general question in Part B of the questionnaire about whether source water is impacted by agrichemicals, EPA should also consult GIS coverages of land use/cover (crops, golf courses, utility right-of-ways, etc.) and animal feeding operations to help assess these impacts. Part B also asks for data on previous emerging contaminant analyses. This should be clarified to ask about unpublished or internal data so that utilities do not have to spend time reporting data that is available in published studies or databases from government agencies.

The questionnaire should not just be submitted electronically, but should be provided as an editable document (a pdf where you can type in responses) to make it easier to complete and return.

### **Response to Collective Comment 1**

As federal employees, the investigators involved in this project must follow the PRA when collecting information from more than nine respondents. Gaining Information Collection Rule (ICR) clearance is a long process (estimated to take nine months). The questionnaire was designed to capture all information we considered necessary to later interpret the analytical data, in order to avoid having to go through a second ICR clearance process to ask subsequent follow-up questions. Engineers within the EPA

were consulted to ensure we asked relevant questions about the treatment processes used in the drinking water treatment plants (DWTPs). Questions concerning population, disinfectant, etc are included in the questionnaire document the diversity of populations and processes within the DWTPs involved in the study. The majority of the emerging contaminants in this study (see Comment / Response 4, below) are primarily introduced into the environment through household wastewater, be it through a municipal WWTP, or on-site wastewater treatment. To better qualitatively evaluate the impact of drinking water treatment on pharmaceuticals and other contaminants in wastewater effluents, the study will be intentionally skewed towards facilities whose sources are known to be impacted by upstream discharges of human waste, thereby increasing the potential for detection in the source water. Thus, documenting local knowledge of waste sources potentially impacting each DWTP is important.

In preparing a list of candidate sites, the investigators on this project are working with their regional colleagues in the USGS and EPA to assess background information such as livestock production and land use, as well as obtain information on recent and on-going sampling studies being conducted at the DWTPs.

In many cases, the data that is reported by utilities to the EPA's Office of Water, and other state and tribal authorities. This information is not available to the investigators in this project. We do not ask for the data to be formatted in any particular way, just to recapitulate what they have already prepared. We would not expect this to be a difficult item, in terms of time or burden, to fulfill.

The questionnaire posted in the docket was generated using the default Federal Docket Management System pdf generator. The participating utilities will be given a pdf they will be able to fill out electronically, as well as a paper copy on which they can hand write the information. We prefer the electronic submission, but will accept either.

## **Collective Comment 2: Freedom of Information Act**

***Commenter A.** Drinking water utilities are very concerned that the limited information developed as a result of this information collection could be obtained via a Freedom of Information Act (FoIA) request and be misinterpreted. The data reported out of context could be very difficult for the utilities to explain to the media and the public.*

***Commenter C.** The Supporting Statement for the questionnaire includes a provision for confidentiality of the utility. However, this is not explicitly included in the Federal Register Notice. This should be included in the final notice to allay concerns over public relations issues based on the result of a single sample.*

## **Response to Collective Comment 2**

As this project is a federal work product, it is subject to Freedom of Information Act (FOIA) requests from the public. We plan to inform the DWTPs at the outset that while we intend to preserve their anonymity to the best of our ability, a FOIA is a possibility. If the project is FOIA'd we will work with the DWTPs to make sure they can provide quick and accurate responses to questions which may be generated by their consumers and local media.

Prior to publication of the data in a peer reviewed journal and/or EPA/USGS data reports, we will give all DWTPs a copy of their analytical data, and provide them the opportunity to comment on the manuscript(s) that will be generated. As with all studies, once the data is published we cannot control how the data is used or misused by others. We are doing all we can to ensure that our publication(s) fairly and accurately summarize the data.

### **Collective Comment 3: Utility Burden Cost Estimates**

*Commenter A. Finally, the cost estimates reflect industry wide averages, which can be influenced by system size. Cost estimates should be modified to reflect costs in those size utilities likely to participate. Given that larger utilities will probably be most likely to volunteer for a study like this one, the basis for this effort's cost estimates should be based on larger utilities.*

### **Response to Collective Comment 3**

We are unsure if this comment is implying the cost estimates are too high or too low. We were only able to find one source of salary data, which was the median annual salaries reported by the American Water Works Association (<http://www.awwa.org/careercenter/resources/docs/JobDescriptions.cfm>). In a previous study of nine DWTPs, we were able to partner with utilities ranging in size from those producing less than 1 million gallons per day (MGD) to more than 90 MGD, serving populations ranging from 12,000 to 1.2 million. For this study, we hope to obtain a similar range of production size and sophistication, so we think the median salaries are applicable.

The cost estimates have been adjusted to include initial phone interviews that will be used to finalize the candidate list. The times allotted for each activity have also been increased to hopefully over-estimate the burden on the DWTP respondents.

### **Collective Comment 4: Specific Analytes and Methods Used During Project**

*Commenter A. There is no list of "emerging contaminants" to be sampled or laboratory methods to be used.*

*Collecting occurrence information without standard sampling and analytical methods is risky at best. If the analytical methods used for this effort do not ultimately qualify*

*as an agency approved method, will the data be of use to the agency for future policymaking?*

*Although USGS and EPA staff indicated that the study design includes rigorous quality assurance and quality control, this information is not provided in the docket.*

**Commenter B.** *As drafted, the information collection activity targets “emerging contaminants.” The docket for this information collection request does not include a description of the sampling or analytical method(s) or target analytes that the effort would obtain. Absent a clear understanding of what analytes are being measured, it is difficult to determine if occurrence data are relevant to EPA’s activity under the SDWA, Clean Water Act (CWA), or other regulatory programs.*

#### **Response to Collective Comment 4**

We are currently planning on using a suite of chemical and microbiological methods to analyze the water samples collected in this project for over 200 analytes, including:

- 117 prescription and nonprescription pharmaceuticals and their metabolites
- 17 perfluorinated compounds
- 13 industrial chemicals
- 11 fragrances
- 9 polycyclic aromatic hydrocarbons
- 8 hormones
- 8 pesticides
- 7 detergent related chemicals
- 7 household chemicals
- 4 plant and animal sterols
- 3 phosphorous based flame retardants
- 1 nanomaterial
- 5 bacteria
- 3 fungi
- 2 protozoa
- 2 viruses

Included as Attachment B in the public docket for this ICR (No. EPA-HQ-ORD-2009-0114) is a bibliography of the published analytical methods that will be used on this project, as well as a listing of the analytes that are contained in those methods. Several methods are still in the development process; the analytes listed in those methods are not specifically included in the listing as some chemicals may be found to be unsuitable, and will subsequently never be reported.

For this project, we have incorporated a very high level of quality control and quality assurance samples to ensure we will be collecting accurate and defensible analytical data. For the chemical methods, all samples will be collected in triplicate; one sample will be analyzed as the primary sample, the second as a duplicate, and the third will be



spiked with the analytes to evaluate matrix interferences. In addition, a sample of certified laboratory water from the same lot will be shipped to each location as a field blank. The utilities will be instructed to decant the laboratory water into sample bottles, to mimic any contamination that may come from the personnel during sampling. To aid in comparability, all methods will use the same method of evaluating their lowest level of detection- either the EPA method detection limit (MDL; U.S. Environmental Protection Agency, 2005, Guidelines establishing test procedures for the analysis of pollutants (App. B, Part 136, Definition and procedures for the determination of the method detection limit): U.S. Code of Federal Regulations, Title 40, revised as of July 1, 2005, p. 319–322.), or the newer EPA Lowest Concentration Minimum Reporting Level (LCMRL). The MDL estimates a detection limit based upon a method’s precision, while the LCMRL estimates a detection limit based upon the precision and accuracy of a method, but requires four times as many samples to calculate. In all, considering the duplicate sample, matrix spike, field blank, laboratory blanks and spikes ran with every batch of samples, and the MDL or LCMRL samples, well over 70% of the samples analyzed as part of this project will be used for quality control purposes.

Fifty of the over 200 chemicals that will be measured in this project are analytes in two (35 compounds), three (13), or four (2) analytical methods. The overlap between methods will provide another check on the performance of the methods, and will give greater certainty to the resulting concentration data.

Methods used for drinking water regulatory purposes meet a stricter requirement for ruggedness than methods typically published in the literature. The regulatory method development process typically evaluates different extraction materials and analytical columns from multiple vendors, focuses on wide ranges of pH and carbon content, evaluates different de-chlorination agents and biocides, and conducts extended (28 day) holding time studies. Once the method is developed, it is evaluated by two to four other laboratories to ensure the written procedure is clear, and the method able to be successfully performed by other analysts. Any analyte that will be under consideration for regulation must go through this development process, regardless of the number of existing methods currently present in the literature. However, the methods used in this project could potentially be used as starting point for the drinking water regulatory method development process.

#### **Collective Comment 5: Utility of the Data to the EPA**

***Commenter A.** In speaking with USGS and EPA staff overseeing the study, it is AMWA’s understanding that the results of the study will be used to inform EPA’s Office of Water in selection of contaminants for the Unregulated Contaminant Monitoring Rule (UCMR) or Contaminant Candidate List (CCL). The information collection activity’s supporting statement says that the results of the study will help EPA “determine which chemicals should be considered for future regulation in drinking water.” However, there is nothing in the docket about the study design or rationale or how the study might be used to inform policy.*

*AMWA supports the UCMR and CCL processes. There are many required elements for a contaminant to make the UCRM list and/or the CCL. The criteria that a contaminant must meet to make the list are extensive. AMWA recommends that additional work be performed to develop this study so that it better fits within the construct of existing regulatory programs under the Safe Drinking Water Act, as well as programs under the Clean Water Act. As currently constructed, AMWA believes that the proposed data collection would mislead EPA's effort for identifying and prioritizing contaminants that should be further evaluated. The following comments provide additional concerns about the proposed study and suggestions for its improvement.*

*In summary, AMWA believes that the study as described in the Federal Register notice is inadequately defined in the docket. As a result, the study could mislead EPA's effort for identifying and prioritizing chemicals to be further evaluated. AMWA recommends that EPA provide additional information in the docket describing the study hypothesis, design, sampling and analytical methods, and purpose. AMWA also believes that the study is potentially misdirected toward characterizing diluted drinking water supplies instead of characterizing more concentrated contaminant sources. This should be reconsidered and a rationale described in the revised notice and docket. In addition, AMWA recommends that this study build upon currently published data or studies currently underway by others. In light of these concerns, AMWA suggests that this study is insufficient to provide information of practical utility or necessity for the "proper performance of the functions of the Agency." Once these issues have been addressed, another request for comment should be issued before proceeding with the study.*

**Commenter B.** *AWWA's primary concerns are with respect to the first three of these questions. The information provided in the docket indicate that roughly 50 water systems will be provided a questionnaire and that those same utilities will provide water samples for the analysis of an unknown list of contaminants. EPA's Safe Drinking Water Information System (SDWIS) indicates that there are more than 51,970 community water systems (CWS) and an additional 102,865 non-community water systems (NCWSs). More than 11,670 CWSs rely on surface water supplies. Given the large number of water systems, it is not clear that a sample design based on 50 locations would "have practical utility." It is worthwhile to note that EPA has a much more robust sampling mechanism under the Safe Drinking Water Act (SDWA) known as the Unregulated Contaminants Monitoring Rule (UCMR). EPA has successfully used the UCMR mechanism to collect data from all systems serving greater than 10,000 people and from a statistically valid sample of smaller CWSs to guide federal drinking water policy development.*

## **Response to Collective Comment 5**

The commenter is correct that there are criteria the Agency has established to consider contaminants that may require regulation as it implements the Contaminant Candidate

List (CCL) or Unregulated Contaminant Monitoring Rule (UCMR). The EPA's Office of Water (EPA-OW) evaluates and identifies which chemicals should be considered for regulation in drinking water in the United States. The results produced in this study will be one part of a comprehensive evaluation of chemical occurrence data collected to help EPA "determine which chemicals should be considered for future regulation in drinking water."

The EPA is required to publish, every five years, a list of contaminants (1) that are currently unregulated, (2) that are known or anticipated to occur in public water systems, and (3) which may require regulation under the Safe Drinking Water Act (SDWA). That list is the CCL.

EPA evaluates both health effects and occurrence information to identify a broad universe of contaminants and select contaminants for inclusion on the CCL. The Agency considers chemicals whose properties, occurrence in water supplies, and environmental chemistry indicate that they meet the three criteria discussed above. The Agency interprets the criterion that contaminants are known or anticipated to occur in public water systems broadly. In evaluating this criterion, EPA considers not only public water system monitoring data from the UCMR, but also data on ambient concentrations in surface and ground waters, and releases to the environment (e.g., Toxics Release Inventory). The Agency anticipates that results from this survey will provide additional valuable information to consider for future CCLs. While such data may not establish that contaminants are known to occur in public water systems at a national level, EPA believes these data will be sufficient to anticipate that contaminants may occur in public water systems. The Agency will use these and other data to evaluate and consider potential candidate contaminants for inclusion on the CCL. Once contaminants have been placed on the CCL, EPA identifies if there are any additional data needs, including occurrence data, to determine if a regulation should be developed.

The commenters are correct that EPA-OW can monitor for unregulated contaminants under the UCMR. The UCMR is unparalleled in terms of gathering a statistically representative sampling of drinking water in the United States; however, it is limited to a 30 contaminant maximum. Under the UCMR, EPA may require monitoring of up to 30 potential drinking water contaminants, during each 5 year UCMR cycle. The UCMR program is currently designed to assign contaminants to one of three different levels of monitoring, based upon the cost of performing the analysis, the availability of analytical methods, and the capacity of the commercial laboratory system to perform these analyses. All public water systems (PWSs) serving more than 10,000 people and 800 representative PWSs serving 10,000 or fewer people are required to conduct the first level of monitoring, known as "Assessment Monitoring." All large PWSs serving more than 100,000 people, 320 large representative PWSs serving 10,001 to 100,000 people, and 480 small representative PWSs serving 10,000 or fewer people are required to conduct the second level of monitoring known as the "Screening Survey". The third level of monitoring is reserved for those contaminants which require monitoring using very expensive or very limited use analytical technologies. To fully

evaluate the 200 chemical and microbial contaminants included in this project through UCMR monitoring would be highly impractical; given the 30-contaminant maximum and the 5-year UCMR cycle, it would take seven UCMR cycles over the course of 35 years. The Agency anticipates that the results of this study will provide additional information on analytic methods and the occurrence of PPCP chemicals in drinking water to help identify contaminants for consideration under future UCMRs .

We concur that this project will not have the statistical strength to singly quantify removal percentages by the different treatment techniques used at the DWTPs. However, the results of this study will provide qualitative information for EPA and the research community at large to design more comprehensive studies to demonstrate whether advanced treatment increases the removal efficacy for these compounds, as compared to conventional treatment.

Since the publication of a series of articles by the Associated Press discussing the presence of pharmaceuticals in the environment and in drinking water, the American public, as well as Congress, have become more aware of the topic and have raised questions about the presence and human health impact of these compound in drinking water. There are currently two bills which have passed in the House of Representatives and have been referred to Senate committees for deliberation. The National Water Research and Development Initiative Act of 2009 directs federal agencies to collaborate on water quality issues including:

H.R. 1115, § 2(d)(19): Improvement of understanding of the impacts from chemical impairments, including contaminants of emerging concern, such as endocrine disrupting compounds, pharmaceuticals, and personal care products, on water supply and quality.

The second bill, the Water Quality Investment Act of 2009, is directed toward amending the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.), includes the following mandates for the EPA:

H.R. 1262, Title VI § 6001: Presence of Pharmaceuticals and Personal Care Products in Waters of the United States.

Section 104 [of the Federal Water Pollution Control Act] (33 U.S.C. 1254) is amended by adding at the end the following:

‘(w) Presence of Pharmaceuticals and Personal Care Products in Waters of the United States-

‘(1) Study- The Administrator, in consultation with appropriate Federal agencies (including the National Institute of Environmental Health Sciences), shall conduct a study on the presence of pharmaceuticals and personal care products (in this subsection referred to as ‘PPCPs’) in the waters of the United States.

‘(2) Contents- In conducting the study under paragraph (1), the Administrator shall--

‘(A) identify PPCPs that have been detected in the waters of the United States and the levels at which such PPCPs have been detected;

‘(B) identify the sources of PPCPs in the waters of the United States, including point sources and nonpoint sources of PPCP contamination; and

‘(C) identify methods to control, limit, treat, or prevent PPCPs in the waters of the United States.

‘(3) Report- Not later than 12 months after the date of enactment of this subsection, the Administrator shall submit to Congress a report on the results of the study conducted under this subsection, including the potential effects of PPCPs in the waters of the United States on human health and aquatic wildlife.

‘(4) Pharmaceuticals And Personal Care Products Defined- In this subsection, the terms ‘pharmaceuticals and personal care products’ and ‘PPCPs’ mean products used by individuals for personal health or cosmetic reasons or used to enhance growth or health of livestock.’.

Of the over 200 analytes in this project, 125 are pharmaceutical related chemicals (pharmaceuticals, pharmaceutical metabolites or hormones). EPA personnel are currently compiling a review of studies conducted in the United States and published between 2001 and January 2009 that measured pharmaceutical related chemicals in wastewater, surface water, and ground water (Kostich et al, in preparation). In the literature review, 110 pharmaceutical based chemicals were analytes in at least one study. Fifty-six of the 125 pharmaceutical based compounds in this study overlap with those found in the literature review; over 60 of the pharmaceuticals in our study have no reported occurrence information in ground, surface, and waste-water in the United States. An even smaller number of chemicals have been measured in finished drinking water, and chemical occurrence data are needed to assess the potential of effects to human health, as outlined above. If passed, H.R. 1262 provides a very narrow window of time to produce a report on the occurrence of pharmaceuticals in the nation’s waters, this study will be a valuable asset to provide the most comprehensive, timely report possible.

Before commencing, this project was reviewed by panel consisting of two independent reviewers from academia, two from the EPA-OW and one from EPA Region IX and was found to be of use to the Agency.

## **Collective Comment 6: Data on Emerging Contaminants in Peer-Reviewed Literature**

**Commenter A.** *In recent years there have been many studies published in the scientific literature concerning the occurrence of pharmaceuticals and other emerging contaminants in the water environment. AMWA recommends that the EPA include in the docket documentation about how this study will advance the current body of knowledge and be useful for the mission of the agency. If EPA plans to use the occurrence data to build upon work that has already been done or build a database of emerging contaminants, then this information should be conveyed.*

*The Water Research Foundation has a strategic initiative focusing on various aspects of Endocrine Disrupting Compounds / Pharmaceuticals and Personal Care Products (EDC/PPCP). Two projects in this initiative could have an impact on EPA's proposed work. One is a laboratory round robin to determine commercial laboratory capabilities. The second is the development and execution of a statistically based monitoring program looking at a variety of EDC/PPCP inputs to the watershed.*

**Commenter B.** *AWWA's member utilities, EPA, the Water Research Foundation, and numerous other entities are engaged in research on the potential health effects and occurrence of an extraordinary list of manmade and naturally occurring compounds. At present, the breadth of that research is so large as to virtually preclude meaningful progress toward federal risk management policy determinations. We urge that this information collection effort (EPA ICR No. 2346.01) not proceed until such time as an experimental design that offers a strong contribution to EPA's information needs can be clearly articulated and supported. In our view, such a study must have clearly articulated hypotheses which will be tested, demonstrate adequate statistical power to support its conclusions, and data collection using methods of known precision and accuracy. In reviewing the available data on "emerging contaminants" the key data that would be most useful at this time is not additional occurrence data, but whether there is any human toxicological relevance at observed environmental concentrations.*

**Commenter C.** *The proposed plan appears to ignore extensive data that has been collected over the past few years on the occurrence of emerging contaminants by various organizations including some federal agencies. Some, if not most, of those data collection efforts include more than single event sampling and could provide more useful data. Some of this information is already available from EPA's own databases, USGS publications and possibly, source water assessment reports.*

### **Response to Collective Comment 6**

We disagree with the comments that there is sufficient information in the scientific literature concerning the occurrence of emerging contaminants, particularly pharmaceuticals, in the finished drinking water of the United States. While research has been conducted to determine that such compounds can be present in finished drinking water, much is yet to be understood in terms of fully documenting the full range of chemicals present in source and finished drinking water, the composition of

complex mixtures of contaminants potentially present, determining the effects of drinking water treatment, and understanding important factors contributing to such contamination.

The USGS has published several studies related to drinking water (Stackelberg et al., 2004, 2007; Focazio et al., 2008) documenting that a wide range of emerging contaminants (including pharmaceuticals) are present in source water and survive drinking water treatment. Ye et al (2007) sampled 24 antibiotics at three DWTPs, detecting six of them at least once in the finished water. Benotti et al (2009) has published the most comprehensive study in the United States to date, targeting 51 compounds in 19 DWTPs; twenty of these chemicals, including nine pharmaceuticals, were detected at least once in finished water. In the Associated Press' series of articles on pharmaceuticals in drinking water published in 2008, 34 out of 62 major metropolitan areas in the United States have not tested their water for a single pharmaceutical. Clearly there is a deficit in the determination of occurrence of these compounds in finished drinking water.

The EPA/USGS research of drinking water across the United States will be targeting over 200 chemicals, more than 170 of which were *not* analytes in the Benotti et al study. One of the concerns with emerging contaminants is not the presence of individual compounds, but the potential effects of simultaneous exposure to complex mixtures of a wide ranging of chemicals. The comprehensive suite of chemicals analyzed in concurrently collected samples will begin the process of identifying what plurality of chemicals can exist in finished water.

In October 2007, the American Water Works Research Foundation (now renamed the Water Research Foundation (WRF)) convened a workshop to prioritize research needs for pharmaceuticals and EDCs (<http://www.waterresearchfoundation.org/research/TopicsAndProjects/Resources/ResearchPlan/EDCStrategicInitiative/EDCWorkshopReport.pdf>). More than 30 experts from the drinking water industry, academia, consulting firms, and government in the field of pharmaceutical and EDC research submitted 41 projects to be considered for future research; of these, 28 were fleshed out as potential projects to be funded by WRF. A project similar in scope to the EPA/USGS sampling program, "Characterization of Source Water Quality, Finished Water Quality and Treatment Process Effectiveness" was rated highest of the eight projects Source Water Protection and Occurrence Focus Area, and was overall ranked seventh out of the 28 projects.

The WRF project on analytical method inter-comparability was one of the other 27 projects nominated at the 2007 workshop. The round robin project was nominated at the workshop by one of the PIs involved in the EPA/USGS sampling project, and who is currently a member of the project advisory committee. As mentioned in the Response to Comment 4, this project will also generate valuable information on interlaboratory method comparability. While this study will not have the same breadth of participants as the WRF project, the uniformity in QA/QC parameters the EPA/USGS study as well as the number of overlapping analytes (50) will provide

information that complements the WRF project. As a team, we are interested in the results of the WRF projects, and will monitor the literature for their results.

### **Collective Comment 7: Sampling Design**

**Commenter A.** *The Federal Register notice states that emerging contaminants (ECs) “are chemicals... which are excreted from or washed off the body and enter the wastewater treatment system.” This statement is inaccurate, as many of the ECs of concern in our watersheds are generated by other sources, such as agricultural business. AWWA also suggests that the study include source water characterization at sites considered to be point sources for these compounds. By the time many of these contaminants reach drinking water intakes, their concentrations have been attenuated by dilution, making them difficult to detect. Characterizing point source discharges before they are diluted by the receiving water is important information that can be used by EPA’s water program in implementing the watershed approach framework.*

**Commenter B.** *AWWA’s primary concerns are with respect to the first three of these questions. The information provided in the docket indicate that roughly 50 water systems will be provided a questionnaire and that those same utilities will provide water samples for the analysis of an unknown list of contaminants. EPA’s Safe Drinking Water Information System (SDWIS) indicates that there are more than 51,970 community water systems (CWS) and an additional 102,865 non-community water systems (NCWSs). More than 11,670 CWSs rely on surface water supplies. Given the large number of water systems, it is not clear that a sample design based on 50 locations would “have practical utility.” It is worthwhile to note that EPA has a much more robust sampling mechanism under the Safe Drinking Water Act (SDWA) known as the Unregulated Contaminants Monitoring Rule (UCMR). EPA has successfully used the UCMR mechanism to collect data from all systems serving greater than 10,000 people and from a statistically valid sample of smaller CWSs to guide federal drinking water policy development.*

*The available information suggests that a single influent and a single finished water sample will be taken to characterize each participating water treatment plant. If the agency anticipates utilizing the survey data in combination with the measured occurrence data, then it seems implausible that that the limited number of observations and the small number of sample locations will support a meaningful analysis. Many samples at each sample location would be needed to account for differences in observed values due to the variability resulting from the analytical method, elapsed time, and treatment processes. Indeed, if it is the researcher’s intent to characterize treatment efficacy, then typically pilot plant testing offers a much more robust experimental design. Though, in both experimental approaches a much larger number of samples is required to address inherent sources of variability.*

**Commenter C.** *Furthermore, the study design implied by the ICR (a one-time sampling event of source and treated water at each of 50 drinking water treatment plants - DWTPs) is not adequate to meet the intended goal of using the results to*



*advise the EPA in determination of chemicals to consider for future regulation. We do not believe that 50 samples from volunteer water utilities (not selected through any sort of stratified random sampling) will adequately characterize emerging contaminant occurrence in any sort of meaningful way. This approach assumes that DWTPs deal with steady-state conditions and it also ignores seasonal and analytical variability. More frequent sampling for a year (monthly?) at fewer sites is suggested as an alternative.*

*The Metro Utility Committee also has problems with the study's proposed use of paired (raw and finished water) sampling and a detailed questionnaire/survey at each utility for EPA "to help interpret the data collected during the water sampling program." The questionnaire appears to be aimed at collecting information that could be used to draw conclusions about treatability, as opposed to occurrence. Such conclusions, we believe, would be inappropriate, given the limited number of samples to be collected.*

*Consider the example of a contaminant that is detected in the source, but not finished water, in a single paired sampling event. This result could be due to the treatment process removing or transforming the contaminant. It could also be due to fluctuating source water contaminant concentrations and imperfect sampling timing. Or it could be due to irreproducible analytical variability near the analytical method's detection limit (which is common when sampling for trace contaminants). Likewise, a contaminant that occurs in the finished water but not the source water could have been a trace byproduct created during treatment or contributed by treatment chemicals, or again, an artifact of sample timing and source water contaminant level fluctuations. It could also be due to the cleaner finished-water matrix allowing for improved detection.*

## **Response to Collective Comment 7**

The phrase "emerging contaminants" is an overarching term with no formally established definition. For this project, we are focused on chemicals that are commonly used in households, and have defined emerging contaminants as such.

We concede that the fact that this project will only involve sampling at a minute percentage of the DWTPs in the United States. The funding needed to conduct a sampling exercise on the scale of the UCMR orders of magnitude greater than available for this project. Should the legislation discussed in the response to Collective Comment 4 provide an additional influx of funding for this project, we will increase the number of sampling locations, as well as the number of target analytes. In designing this project, however, we have consciously made design decisions to produce what was felt to be the most useful study possible given the funding available.

- As discussed in the response to Collective Comment 4, we have devoted a large percentage of our budget to the analysis of QA/QC samples, resulting in the generation of strongly defensible data.

- It was decided that the project would be better served by maximizing the number of DWTPs rather than repeated samplings at fewer utilities. However, up to five of the nine DWTPs mentioned in the response to Collective Comment 3 will be re-sampled in this project. While only 83 of the 205 analytes in this study were measured in the previous study, this provides some information on the annual variability emerging contaminants in source and finished waters.
- As mentioned in the response to Collective Comment 1, the sampling network is biased towards DWTPs that have a known or suspected wastewater source in their drinking water resource. Again, as funding is limited, it was felt that the attention should be focused at the upper boundary (worst case scenario) of potential detections and concentrations in source and finished drinking water. DWTPs that draw their source water from aquifers containing older water or have no immediate waste source in their drinking water resource should be very minimally impacted by the chemicals in this study.
- As noted above in the response to Collective Comment 5, the results produced in this study will be one part of a comprehensive evaluation of chemical occurrence data collected to evaluate whether a chemical should be considered for evaluation under the CCL or UCMR. Before any compound would be considered for regulation in drinking water, they would be thoroughly vetted through the CCL and UCMR processes.
- Statistical comparisons of source and finished water for individual compounds will only be performed on the sample set as a whole, using nonparametric statistical tests, such as the Wilcoxon paired sample test.

**(iii) EPA Action Resulting from Public Comment**

In response to the comments received to the first Federal Register Notice, we have made the following changes to the ICR package:

- (a) Section 1(b), Short Characterization/ Abstract, has been modified to include more details about the sampling project that is associated with this information collection.
- (b) Section 6, Estimating the Burden and Cost of the Collection, has been revised to include an initial phone interview, as well as to allow more time to complete the questionnaire.
- (c) A file listing the methods that will be used on this project, as well as the analytes of interest, has been included as Attachment B in the supporting material in the docket.

**3(c) Consultations**

A smaller sampling project used an earlier draft of this questionnaire in 2007. The submissions of the nine respondents from that earlier study were used to modify the questionnaire into its current form.

**3(d) Effects of Less Frequent Collection**

This ICR is a one time only data collection activity for the respondents.

### **3(e) General Guidelines**

The information gathered will be in accordance to the *EPA's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. These guidelines were developed by the EPA to comply with the Office of Management and Budget Guidelines (67 FR 8451, February 22, 2002).

### **3(f) Confidentiality**

The finished questionnaires will not contain any data that should be considered as confidential business information. The questionnaires will be collected and maintained by a single principal investigator. Every DWTP will be assigned a number (such as DWTP 1) to maintain anonymity in data presentations and publications. The DWTPs participating in the study will be given a copy of the manuscripts generated during the study prior to their publication.

### **3(g) Sensitive Questions**

No sensitive questions pertaining to a personal nature will be asked in the questionnaire.

## **4. THE RESPONDENTS AND THE INFORMATION REQUESTED**

### **4(a) Respondents**

The respondents for this study will be a maximum of 50 DWTPs operating in the U.S. and U.S. territories.

### **4(b) Information Requested**

#### **(i) Data Items**

The questionnaire and phone survey used in this study are attached as Attachments C and D. The data to be collected fall into four different categories: 1) utility contact information; 2) utility geographic and demographic information; 3) utility treatment information and 4) general water quality parameters already monitored by the utility at time of sampling.

#### **(ii) Respondent Activities**

Prior to selection, each DWTP will participate in a phone interview to determine if the facility is an acceptable candidate for the project. Once selected, each respondent will receive an electronic copy of the questionnaire when they are notified that sampling supplies have been shipped to their location. Included with the sampling supplies will be a second hard copy of the questionnaire. Detailed instructions will be provided on how to collect and package samples of the DWTP's source and finished water. The questionnaire should be completed concurrent with sampling. The current water quality parameters requested in Part

D of the questionnaire are routinely monitored by DWTPs. The geographic, demographic and treatment information should be historical information the utility has in their records. Respondents may complete and submit the questionnaire either electronically or by mail, with the electronic submission preferred.

## **5. THE INFORMATION COLLECTED- AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT**

### **5(a) Agency Activities**

The EPA's Office of Research and Development will be responsible for administering the questionnaire, answering respondent questions, reviewing respondent answers, and analyzing and storing the data.

### **5(b) Collection Methodology and Information Management**

Each participating DWTP will receive both an electronic and hard copy of the questionnaire. The DWTP can complete the questionnaire by legibly handwriting or typing the responses in the spaces provided, or they may use the electronic version. The questionnaires may be returned via first class mail or e-mail, with electronic submissions preferred.

EPA will include an e-mail address and phone number in the instructions that respondents can use to request assistance in completing the questionnaire. Using these assistance methods enables the respondents to receive a timely response to any inquiries that they may have. E-mail and telephone communication will also reduce any misinterpretations of the questionnaire and thus decrease the burden of follow-up phone calls and letters to the respondents.

Upon receipt of completed questionnaires, EPA will review the questionnaires for completeness.

### **5(c) Small Entity Flexibility**

Many, if not most, of the DWTPs that will be respondents to this ICR can be classified as small businesses under the Small Business Administration's size standards. The EPA has taken several steps to minimize the burden of responding to this questionnaire for all respondents, including small businesses. The questions are phrased with commonly used terminology, and examples of the type of answers that are requested are given. Questions of a similar nature are arranged together to facilitate review of pertinent records.

### **5(d) Collection Schedule**

After OMB approval, between one and three respondents will be contacted each week, and they will each have two weeks to return the questionnaire. Therefore, collection is expected to require a maximum of 365 days.

**6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION**

**6(a) Estimating Respondent Burden**

Based on discussions with the respondents to previous questionnaires, it is estimated that each utility will spend an average of 19 hours completing the questionnaire. In addition, there will be a 1 hour phone pre-interview to explain the project to the DWTPs, inquire about some general information about the DWTPs to determine if they would be acceptable candidates for the project, as well as to ascertain if the DWTPs would want to participate in the study. This burden will likely be spread among several labor categories, both managerial and technical. The Agency estimated the required response time for each labor category in Table 1. The overall project burden is expected to be 1000 hours.

<i>Respondent Job Category</i>	<i>Median Annual Salary</i>	<i>Calculated Hourly Salary</i>	<i>Per Site Burden Hours</i>	<i>Per Site Cost</i>	<i>Estimated Number of Respondents</i>	<i>Overall Project Burden Hours</i>	<b>Overall Project Cost</b>
Operations and Maintenance Executive	\$83,317	\$40.06	2	\$80.12	50	100	\$4,006
Water Operations Manager	\$61,373	\$29.51	8	\$236.08	50	400	\$11,804
Water Quality/Laboratory Manager	\$56,877	\$27.35	10	\$273.50	50	500	\$13,675
Total			20	\$589.70		1000	\$29,485

**TABLE 1. ESTIMATED ANNUAL RESPONDENT BURDENS AND COSTS**

**6(b) Estimating Respondent Costs**

**(i) Estimating Labor Costs**

Hourly salaries for each of the job categories expected to be impacted by this questionnaire were calculated using median annual salaries reported by the American Water Works Association (<http://www.awwa.org/careercenter/resources/docs/JobDescriptions.cfm> Accessed March 4, 2009). These salaries are presented in Table 1. Using this data, costs are estimated to be \$589.70 per location, resulting in an overall project cost of \$29,485.

**(ii) Estimating Capital and Operations and Maintenance Costs**

The EPA is not requiring the purchase of any equipment or machinery to respond to the questionnaire, therefore capital costs are not expected. Operation and maintenance costs include only photocopying and postage for completed questionnaires.

**(iii) Capital/ Start-up and Operations and Maintenance Costs**

No capital or start-up costs should be associated with this project. The operation and maintenance costs will only be incurred by utilities that choose not to respond electronically. The EPA estimates copying charges of \$1.00 and first class postage of \$4.00 to return the questionnaire. This results in a total cost of \$250 for all 50 respondents.

**(iv) Annualizing Capital Costs**

The EPA estimates that there will be no capital costs associated with responding to the questionnaire.

**6(c) Estimating Agency Burden and Cost**

Table 2 presents an estimate of the burdens and costs that the Agency will incur to prepare and administer the questionnaire, as well as interpret the data generated during the project. EPA salary costs are based on an average GS 13 salary in Cincinnati, OH ([http://www.opm.gov/oqa/09tables/html/cin\\_h.asp](http://www.opm.gov/oqa/09tables/html/cin_h.asp) Accessed March 4, 2009).

**TABLE 2. ESTIMATED AGENCY BURDENS AND COSTS**

<i>Agency Activity</i>	<i>Burden Hours</i>	<b>Cost (Assuming median rate of \$45/ hour)</b>
Prepare and format questionnaire	10	\$450
Publish notice of anticipated ICR in Federal Register and respond to generated comments	40	\$1,800
Plan logistics and coordination	500	\$22,500
Identify and recruit utilities	150	\$6,750
Interagency agreement package preparation and submission	30	\$1,350
Quality assurance and quality control	50	\$2,250
Data interpretation and report preparation	1000	\$45,000
Totals	1780	\$80,100

**6(d) Estimating Respondent Universe and Total Burden and Costs**

The EPA expects to receive a maximum of 50 completed questionnaires. The total burden expected is 1000 hours, and the total labor and operations and maintenance cost of \$29,735 for all respondents.

**6(e) Bottom Line Burden Hours and Costs**

Table 3 summarizes the total burdens and costs that the participating DWTPs and the Agency will incur as a result of the information collection. It also accounts for up to an additional 25 DWTPs that may be contacted during the phone interview, but which either do not meet the sampling criteria, or choose not to participate in the study.

**TABLE 3. TOTAL ESTIMATED RESPONDANT AND AGENCY BURDEN AND COST SUMMARY**

	<i>Number of Respondents</i>	<i>Total Burden Hours</i>	<i>Total Labor Cost</i>	<i>Total Operations and Maintenance Costs</i>	<i>Total Cost</i>
DWTPs phone only	25	25	\$1,002	\$0	\$1,002
DWTPs	50	1000	\$29,485	\$250	\$29,735
<b>EPA</b>		1780	\$80,100	0	\$80,100

**6(f) Burden Statement**

The EPA estimates that the total burden to the 50 DWTP operators for responding to the questionnaire will be approximately 1000 hours, or \$29,735 (including labor and operations and maintenance costs). An additional 25 DWTPs may be contacted during the initial phone interview, which would result in a burden of \$1,002. The EPA estimates that there will be no start-up or capital costs associated with completing and returning the questionnaire.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems to collect, validate, and verify information, process and maintain information, and disclose and provide information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, the EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-ORD-2009-0114, which is available for public viewing at the Research and Development Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Research and Development Docket is 202-566-1752. An electronic version of



the public docket is available through <http://www.regulations.gov>. Use Regulations.gov to view and submit public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select “Advanced Search,” then key in the Docket ID number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, D.C. 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID No. (EPA-HQ-ORD-2009-0114) and OMB control number (2080-NEW) in any correspondence.

## **PART B OF THE SUPPORTING STATEMENT**

### **1. SURVEY OBJECTIVES AND KEY VARIABLES**

#### **1(a) Survey Objectives**

This survey is designed to collect background and treatment information from a small subset of the United States' drinking water treatment plants (DWTPs). These DWTPs will potentially be participating in a joint EPA/USGS research project to analyze source and finished drinking water for a suite of chemical and microbial contaminants. Survey responses will be used to select DWTPs that will participate in the sampling study, as well as provide operational information about the DWTP that will permit interpretation of the analytical results and comparison of locations.

#### **1(b) Key Variables**

The information collected from the DWTPs will be gathered in three segments: 1) a preliminary screening phone call, 2) the main questionnaire, and 3) a detailing of the physical/chemical properties of the water samples at the time of collection. For each of these activities, the key variables are:

- Screening Phone Call
  - Willingness to participate in the study
  - Ability to perform the required water sample collection activities
  - Abbreviated description of treatment process
- Questionnaire
  - Information about the watershed the DWTP draws from, including sources of wastewater and agricultural practices that may impact water quality and current hydraulic conditions
  - Broad scale information on the population the DWTP serves
  - Detailed information on the treatment process, including parameters such as pumpage at sampling, disinfectants used, and the distribution system
- Sample Collection sheet
  - Time and date of collection
  - Common water quality parameters (which the DWTPs are already required to monitor)

These variables serve to document the qualitative characteristics of each utility and will be used to better interpret the analytical data.

### **1(c) Statistical Approach**

A statistical approach was not selected for this survey. There are over 160,000 entities in the United States that are subject to the Safe Drinking Water Act. In this study, we have the resources available to analyze samples from a maximum of 50 locations, or approximately 0.031 % of total number of water providers. As explained in the response to Collective Comment 5 in Part A of the Supporting Statement, the EPA can use the Unregulated Contaminant Monitoring Regulation (UCMR) to gather a statistically representative sampling of DWTPs; however, they can only monitor a maximum of 30 contaminants every five years. This study will be analyzing the water for over 200 contaminants. The water concentration data collected in this study may help the EPA's Office of Water choose the chemicals for consideration in future UCMRs.

Although this project has a limited number of samples and is intentionally biased towards those locations that have known or suspected wastewater contributions in the source water, we will maximize the diversity of the locations chosen to participate. A preliminary list of candidate DWTPs has been drafted and were selected to be diverse in terms of geography, treatment technology, DWTP size, and population served.

### **1(d) Feasibility**

The questions asked of the DWTPs concerning the treatment performed at their utility will require very little effort to compile. For those questions concerning the source watershed that the DWTP may find slightly more difficult to answer, the questionnaire text prompts the utility to supply additional contacts that may be able to better answer the question.

If possible, the survey will be given to the DWTP and returned electronically; if hard copies are required to be sent and returned, the financial burden is minimal. The funds required for the analysis have already been acquired and committed.

The survey will have to be completed just prior to or concurrently with the water sampling at the DWTP. If a utility cannot commit to filing the paperwork at the time of sampling, they will not be included in the study.

## **2. SURVEY DESIGN**

### **2(a) Target Population and Coverage**

To assess the upper boundaries of concentrations of emerging contaminants in source and finished drinking water in the United States, we have targeted DWTPs that have known or suspected sources of wastewater in their source water catchment.

## **2(b) Sample Design**

### **(i) Sampling Frame**

The DWTPs selected for the study will be drawn from a master list of candidate facilities compiled by the EPA and USGS project leads. The master list was assembled from a variety of sources including: 1) a EPA document that lists communities with a high percentage of wastewater in their source water (EPA-600/2-80-044); 2) locations sampled in previous EPA and USGS studies known to contain contaminants; 3) nominations by USGS and EPA field and regional personnel; 4) DWTPs that heard about the project and volunteered; and 5) DWTPs mentioned in an Associated Press report that had no emerging contaminant data.

### **(ii) Sample Size**

As currently planned and funded, a maximum of 50 DWTPs will be sampled in this study. The majority of the costs associated with this study will be spent on analyzing the water samples. Even though the sample design is biased towards locations that should have the chemicals we are interested in studying, the concentrations are still expected to be very low, typically in the parts-per-trillion range. To provide the most defensible data set possible, we chose to increase the number of quality control samples that will be collected as part of the project, at a cost of having fewer locations sampled. For this project, for every primary sample analyzed, a duplicate and a matrix spike sample will also be analyzed. Additionally, blank samples will be analyzed from every location to monitor sampling contamination. In all, over 70 % of the samples analyzed in this project will be for quality control purposes.

### **(iii) Stratification Variables**

There are no stratification variables used for this project.

### **(iv) Sampling Methods**

This project is not designed to be representative of the DWTP community as a whole; it is intentionally biased to locations with known sources of wastewater in its source water, with the specific purpose of maximally characterizing potential wastewater impacts on source waters. Therefore, the nonrandom method of site selection is appropriate.

### **(v) Multi-Stage Sampling**

This survey depends on the voluntary participation of DWTPs. Utilities contacted for the initial screening phone survey may choose not to participate in the full study, or we may discover information that would make them ineligible for this study. Therefore, this study will have two stages, 1) the screening phone survey and 2) the full questionnaire. For both stages, the sample design described above in sections 2.b.i through 2.b.iv will apply.

## **2(c) Precision Requirements**

### **(i) Precision Targets**

This project is not designed to provide a statistical projection to the population of DWTPs at large. Therefore, a target for precision is not appropriate.

## **(ii) Non-sampling Error**

The responses gathered in this survey are specific to each DWTP. Since this project is not designed to provide information on the population as a whole, non-responses will not bias the results.

## **(iii) Questionnaire Design**

The questionnaire used in this study is attached as Attachment C. The data to be collected fall into four different categories: Part A) utility contact information; Part B) utility geographic and demographic information; Part C) utility treatment information; and Part D) general water quality parameters already monitored by the utility at time of sampling. Parts B through D will be used to determine why some contaminants may be present in the source or finished water of one DWTP but not another. For example, the variation in detection could result from differences in the composition of waste sources in the source watershed, or differences in the treatment technologies used. The concentration of the analytes in this study can be influenced by the physical or chemical water quality parameters requested in Part D; this information is necessary to make meaningful comparisons between locations.

Most of the information supplied by the DWTPs will be very site specific. Therefore, the open-ended question format was an appropriate choice for the majority of the questions.

## **3 PRETESTS AND PILOT TESTS**

This project is the second in a two phase project. In Phase I, conducted in 2007, nine DWTPs were sampled; all participants were given an earlier version of this questionnaire. Based on requests for clarification from the Phase I DWTPs, the text of the questions were modified. The layout was also redesigned to facilitate both electronic and hand-written responses.

## **4 COLLECTION METHODS AND FOLLOW-UP**

### **4(a) Collection Methods**

Collection of information from the DWTPs is expected to include both telephone interviews and completion of the questionnaire. The contact with the DWTPs is expected to follow the following scenario:

- A candidate DWTP will be called, and in a short (5 minute) conversation, the project will be briefly described. If the DWTP is interested in participating in the study, a contact e-mail or postal address will be requested so that a fact sheet about the project, a listing of the analytes that will be studied, and information about the methods to be used can be sent. An appointment for a more detailed call will also be made.
- In the second call, the entire EPA and USGS project team will participate. This call will give the DWTP an opportunity to ask specific questions about the project. It also gives the project team the ability to evaluate the capability of the DWTP to collect the

requested samples, as well as find out general information about the utility (for example, what disinfectant is used, but not the dosage or anecdotal information about the watershed). During this call, we will notify the DWTPs that while we intend to maintain the anonymity of each location during sampling, this project is a federal work product, and therefore subject to freedom of information act (FOIA) requests. At this point, both the DWTP and the project team will determine if a location will be included in the project. Information from both the first and second calls will be recorded on the Pre-questionnaire telephone survey, provided as Attachment D.

- The DWTP and project team will agree on a date for sample collection. The questionnaire will be sent to the utility in advance of the collection. Parts A through C can be completed in the week before sampling; Part D should be filled out on the day of sampling. The completed form will be submitted with the samples to the EPA.

#### **4(b) Survey Response and Follow-up**

Due to the site selection process used for this project, a 100 % response rate is expected. The completed questionnaire will be reviewed by the EPA and USGS project leads. If any of the responses are unclear, the DWTP will be contacted either by e-mail or telephone for clarification.

### **5 ANALYZING AND REPORTING SURVEY RESULTS**

#### **5(a) Data Preparation**

Due to the small number of sites sampled, and the variety of expected answers, the questionnaires will be maintained as separate entities, and not entered into a database. However, an overview table will be compiled for use in data reports. This table will likely consolidate the following information: anonymous site identifier, source water type (surface or ground water), source water level at sampling (high, low or average), population served, pumpage at sampling maximum pumpage, disinfectant, disinfectant dose, disinfectant residual, overview of treatment steps and overall plant residence time.

#### **5(b) Analysis**

At the completion of the entire program, a joint USGS and EPA data report will be produced that summarizes all of the contaminant information collected in the study. Several manuscripts interpreting the results of the study will also be produced for publication in peer-reviewed scientific journals. These manuscripts may or may not use the utility information collected as a part of this request to assist in the data interpretation. The participating DWTPs will each receive a copy of the manuscripts, and will be permitted to provide comments prior to submission for publication.