Attachment B1

Public Comments and Agency Responses

We received 7 public comments about this Generic ICR Clearance. The comments and responses, where appropriate, are listed below.

Type of Comment	Submitter Information	Comment	Response
Public Submission	Jean Public <jeanpublic1@yahoo.com> Received: March 11, 2016 Status: Posted Posted: March 21, 2016 Tracking No. 1k0-8omi-x43d	I WANT TO SIGN UP FOR THIS INVESTIGATION OF MY WELL WATER. I BELIEVE THAT THE DRINKING WATER STANDARDS, WHICH HAVE NOT BEEN SUBSTANTIALLY IMPROVED SINCE THE 1930S DO NOT REFLECT THE CURRENT STATE OF WATER. WE HAVE CONTAMINATED AND POLLUTED WATER IN NJ AND OUR GOVERNOR CAME INTO OFFICE SAYING HE WOULD NOT INCREASE ANY REGULATIONS TO CHECK THE ENVIRONMENT. THAT WAS 8 YEARS AGO. WE HAVE MASSIVE AMOUNTS OF CONTAMINATION IN NEW JERSEY. I WOULD LIKE TO SIGN UP TO SEND IN WATER AND ALL THE TESTS THAT ARE INVOLVED. I FAVOR THESE TESTS BECAUSE CERTAINLY THIS IS AN ISSUE OF HEALTH FOR AMERICANS. WE CAN HELP THE HEALTH STANDARDS PERHAPS THIS IS WHAT IS CAUSIGN AUTISM. 1 OUT OF 25 BOYS WHO ARE DEFICIENT MENTALLY. THIS COMMENT IS FOR THE PUBLIC RECORD. PLEASE RECEIPT. JEAN PUBLIEE JEANPUBLIC1@YAHOO.COM	Program responded to commenter in email. **From:** Backer, Lorraine (CDC/ONDIEH/NCEH) **Sent:** Wednesday, June 01, 2016 3:36 PM **To:** jeanpublic1@yahoo.com **Subject:** Response regarding CDC's document CDC-2016-0027-0002 Dear Ms. Public, We received your email with comments regarding CDC's document CDC-2016-0027-0002. We appreciate your interest in participating in a future investigation. If New Jersey is identified as one of the partners for this program, we will be sure to let them know of your interest. Cheers, Lorrie Contact information: Lorraine C. Backer, PhD, MPH National Center for Environmental Health 4770 Buford Highway NE MS F-60 Chamblee, GA 30341 Phone: 770-488-3426 Fax: 770-488-3450

Public Submission	Wenwen Liu Received: March 31, 2016 Status: Posted Posted: April 06, 2016 Tracking No. 1k0-8ote-776v	Since water is the most significant necessities for every one used every day, I think it is important to search health risks from using private wells for drinking water. Drinking water for approximately one sixth of US household is obtained from private wells. These wells might be polluted by potential contaminants, sewage and so on. Although the US Environment Protection Agency and all states offer guidance for construction, maintenance, and testing of private wells, it is hard to know all of the locations of private wells, and the populations served by these wells. Therefore, well owners should be responsible for their own wells such as testing quality of water from wells and taking physical examination regularly. Then after knowing the main reasons what affect the quality of wells water, states or federal related organization could set up some regulations. For instance, set up a organization which helps people test quality of water from their wells. Moreover, if sewage released from factories were one of reason pollute wells, government could set up regulations like factories must clean the sewage lower than a standard level before releasing. Water is one of the most important substances on earth. If there was no water there would be no life on earth. Human beings, of course, must have water to survive. Therefore, I think it is necessary to collect investigations and analyze how some external elements affect private wells then to get the health risks from using private wells for drinking water. And I am very interested in the final research results.	No response required
Public Submission	Jennifer Ervin Received: March 30, 2016 Status: Posted Posted: March 31, 2016 Tracking No. 1k0-8osp-34z6	I think this is a very important and needed study. Unsafe drinking water with contaminants can potentially affect residents for the rest of their lives, as evidenced by the saga unfolding in Flint, Michigan. Having been raised on well water in a rural area, I am naturally curious what potential contaminants could be in water not protected by the Safe Drinking Water Act (private wells). I would be interested in which geographic areas of interest will be determined by the agency, and if it includes any areas in the southeastern region of the United States.	No response required
Public Submission	Misagh Owji Received: April 05, 2016	Current policy In recent year many have showed interest in a more credible scientific based environmental regulation (media,	No response required

	Status: Posted Posted: April 06, 2016 Tracking No. 1k0-8owj-cr8q	1998). Even though our water system has significantly improved in the last century, the government should rely on laboratory testing in government agencies to make sure that the water that we are using is not contaminated. History shows that contaminated water can have a negative effect on the health of the population. For example, in 1800 the annual deaths in London were 110 per 10,000. (Daniel A. Okun) introduction of the flush toilet let to the discharge being dumped in Thames River, this lead to disease including cholera which became airborne and lead to many deaths. In the beginning of this century we have the same issues within our borders. Prior to widespread acceptance of filtration of water AND chlorination, we had a huge issue with typhoid fever deaths. However chlorination and filtration merely killed the airborne disease from spreading. Looking at the history we have a clear indication that we have to continue research and development to stop water borne diseases. The center for disease control is the only agency that not only has the resource but the right scientist that can help with research and prevention of any waterborne disease from spreading. Matter a fact this responsibility should be given to the CDC because one of their duties is prevention and not having the ability to do so can really effect that prevention and preparedness. Historically we have been told to drink eight glass of water per day. there is a huge reason behind that. Kaiser Permanente nephrologist Steven Guest, MD, agrees: "Fluid losses occur continuously, from skin evaporation, breathing, urine, and stool and these losses must be replaced daily for good health," he says. Our focus should be to continuously rehydrate to keep up with loose of water due to the above reasons. Your body is composed of about 60% water. "The functions of these bodily fluids include digestion, absorption, circulation, creation of saliva, transportation of nutrients, and maintenance of body temperature."(Kathleen M.Zelmen). Drinking water can also help control calories and increase metabolism. Other reason water consumption is important is that your muscle fatigue and shrivels with a lack of water consumption. water can also help with keeping your skin	

		looking healthier and younger. In conclusion, Given center for disease control the power to evaluate tap water can help with water borne diseases. Getting us ready for the worst is the job of the CDC and that their always one step ahead of any disease before it comes out is the peace of mind that America and the world needs. Water greatly benefits us and having cleaned none contaminated water will increase the health of the population and possibly increase the life expectancy.	
Email request	**Karlene Lavelle, PhD, MPA, RN** Advanced Scientific Associate Epidemiology and Health Surveillance **ExxonMobil Biomedical Sciences, Inc** 1545 US Highway 22 East Annandale, NJ 08801 908-730-2693 Office 919-270-0116 Mobile Karlene.s.lavelle@exxonmobil.com No Tracking Number available	**From:** Lavelle, Karlene S [mailto:karlene.s.lavelle@exxonmobil.com] **Sent:** Monday, May 02, 2016 2:59 PM **To:** OMB-Comments (CDC) <omb@cdc.gov> **Subject:** RE: Health Risks from Using Private Wells for Drinking Water I have the documents you attached and was requesting attachments referenced within them, for example, Attachment J (research determination form), Attachment G (consent form). Thank you for your further assistance. **Karlene Lavelle, PhD, MPA, RN** Advanced Scientific Associate Epidemiology and Health Surveillance **ExxonMobil Biomedical Sciences, Inc** 1545 US Highway 22 East Annandale, NJ 08801 908-730-2693 Office 919-270-0116 Mobile Karlene.s.lavelle@exxonmobil.com The information transmitted in this message is only intended for the person(s) to which it was addressed and may contain confidential information. If you received this message in error, please delete the message and contact the sender immediately. **From:** Burroughs, Kennya L. (CDC/OD/OADS) [mailto:vhr4@cdc.gov] **On Behalf Of** OMB-Comments (CDC)	Provided the research determination form and the example consent form.

		Sent: Monday, May 02, 2016 2:24 PM **To:** Lavelle, Karlene S **Subject:** RE: Health Risks from Using Private Wells for Drinking Water Please request documents. CDC **From:** Lavelle, Karlene S [mailto:karlene.s.lavelle@exxonmobil.com] **Sent:** Monday, May 02, 2016 2:22 PM **To:** OMB-Comments (CDC) <omb@cdc.gov> **Subject:** Health Risks from Using Private Wells for Drinking Water I am writing in response to a federal register notice vol. 81, No. 48 / Friday, March 11, 2016 page 12902 regarding public comment on "Health Risks from Using Private Wells for Drinking Water. Specifically, can you please provide copies of the consent form and Attachments D, G and Attachment J. Thank you **Karlene Lavelle, PhD, MPA, RN** Advanced Scientific Associate Epidemiology and Health Surveillance **ExxonMobil Biomedical Sciences, Inc** 1545 US Highway 22 East Annandale, NJ 08801 908-730-2693 Office 919-270-0116 Mobile Karlene.s.lavelle@exxonmobil.com 	
Email request	**CropLife America**	May 10, 2016	Steps taken by CDC in response to the

	Beau Greenwood Executive Vice President Government Relations & Public Affairs	Mr. Leroy A. Richardson Information Collection Review Office Centers for Disease Control and Prevention 1600 Clifton Road NE., MS-D74 Atlanta, GA 30329 ***Electronically Submitted via Federal eRulemaking portal*** **RE: Proposed Data Collection Submitted for Public Comment and Recommendations;** **Docket No. CDC-2016-0027** To Whom It May Concern: CropLife America (CLA) appreciates the opportunity to comment on the Centers for Disease Control and Prevention's (CDC) proposed information collection request (ICR) in support of its planned project entitled "Health Risks from Using Private Wells for Drinking Water." 81 Fed. Reg. 12902 (March 11, 2016). Established in 1933, CLA represents the developers, manufacturers, formulators, and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell, and distribute virtually all of the crop protection and biotechnology products used by American farmers. CLA is closely affiliated with its sister organization, Responsible Industry for a Sound Environment (RISE), which represents developers, manufacturers, formulators, and distributors of non-agricultural and human health pest control solutions. CLA also is an active member of the Pesticide Policy Coalition (PPC). CLA supports the CDC's endeavor to achieve greater understanding of the potential health risks associated with the use of private well water, which serves as the primary source of drinking water for over 38 million Americans. CLA has long advocated best practices for protecting private wells on farmland to avoid contamination from spills, siphoning of crop production inputs into chemigation systems, or improperly-closed or abandoned private wells. In the 1990s, a formal wellwater protection program called the Alliance for a Clean Rural Environment was sponsored by CLA and its member companies. The CDC requests public input on the proposed ICR and its	comments: 1. We certainly intend to make use of available data from UGSG and other agencies in any of our studies. 2. CDC will do everything possible to ensure that we recruit an unbiased representation of the community. 3. In collaboration with our public health partners, CDC will identify areas where water quality is of public health concern. 4. This is a request for a Generic ICR Clearance. Specific details about analytes tested in urine specimens, characteristics of wells, other sources of exposure, and timeline for data collection will be specified for each project.

		study, but provides few details about the study design and objectives, which makes it difficult to comment in a meaningful way. CLA nevertheless offers the following comments and recommendations on ways to enhance the usefulness and credibility of the data, so that it may serve as a valuable supplement to the previous studies and available data on both private wells and well water. CropLife America Comments Docket No. CDC-2016-0027 Page 2 of 3 **Representing the Crop Protection Industry** 1156 15th St. N.W. Washington, D.C. 20005 202.296.1585 202.463.0474 fax www.croplifeamerica.org **COMMENTS** **1. The CDC should utilize data from previous studies:** Other federal agencies, including the U.S. Geological Survey (USGS) and U.S. Environmental Protection Agency (EPA), as well as various state agencies, have previously conducted studies on contaminants in private wells. The CDC notes that a comprehensive database is not available, but does not mention previous studies and whether it will consider other sources of data. CLA urges the CDC to review past studies thoroughly, and to account for their findings in its analysis of the data collected in its own investigations. These available studies include, but are not limited to, the following examples: USGS 2009 report, "Quality of Water from Domestic Wells in Principal Aquifers of the United States, 1991-2004." This study assessed 2,100 domestic wells, and measured over 200 properties and contaminants. The study found that 20 percent of private, domestic wells sampled contained at least one contaminant at the level of "potential health concern." National Ground Water Association 2014 report, "Pesticides in Groundwater of the United States: Decadal-Scale Changes, 1993-2011." The study sampled 1,271 wells nationwide and detected pesticides in 53 percent of all samples. Only 1.8 percent of all samples had pesticide detections that exceeded federal human-health benchmarks. EPA's 1992 National Survey of Pesticides in Drinking Water Wells. This study focused on pesticides and nitrates in drinking water wells. EPA found that older and shallower wells near surface waterbodies in agricultural areas were more likely to	

		have detectable levels of pesticides and nitrate. EPA concluded that the overall chance of a given well exceeding a level of concern for a pesticide is low. Iowa Department of Natural Resources, "2013 Survey of Iowa Groundwater and Evaluation of Public Well Vulnerability Classifications for Contaminants of Emerging Concern." This study focused on a large suite of potential contaminants in wells in the state of Iowa. Pesticides were detected in 41 percent of the wells sampled. None of the pesticide detections exceeded human health benchmarks. **2. The CDC should take measures to safeguard against potential biases in the study population.** The proposed ICR lacks detail on how the CDC will recruit respondents for the planned survey, stating only that respondents will be "adults at least 18 years old, who use private wells for drinking water, who are willing to receive and return a tap water sampling kit and urine specimen kit or to provide a blood specimen, and who are willing to answer survey questions," and that the respondents "will be recruited from geographic areas of interest by the requesting agency." CLA is concerned that respondents with chronic health issues unrelated to their drinking water sources may be motivated to volunteer. The CDC should follow a methodology that will ensure an unbiased, random sample population from individuals that rely on private well water in areas of interest. **3. The CDC should be more transparent regarding the geographic bases for these studies.** The proposed ICR indicates that volunteers will be selected from areas of interest, but provides no indication of what those interests and areas are. CLA urges the CDC to strive for geographic variability and to determine if selected areas are unique or representative of other such areas in the CropLife America Comments Docket No. CDC-2016-0027 Page 3 of 3 **Representing the Crop Protection Industry** 1156 15th St. N.W. Washington, D.C. 20005 202.296.1585 202.463.0474 fax www.croplifeamerica.org country. The bases for selection of those areas and elimination of other possible candidates should be detailed. The number and distribution of contaminate sources within selected areas should be	

		examined, as well as the number and distribution of private wells. **4. Other changes and clarifications on the study design and objectives should be made**. The proposed ICR does not describe other important aspects of the methodology, process, and survey questions that the CDC will use in its investigations. CLA urges the CDC to consider the following factors in its survey design, as not doing so could impact the results and reliability of the information gathered: Types of pollutants: The CDC does not indicate which pollutants it will screen for in testing the blood/urine samples collected. The CDC should clarify whether these investigations will focus on a very small sub-set of pollutants, or whether it will measure a wide range of potential well water contaminants. Age and condition of wells: CLA urges the CDC to ensure that any investigation includes an effort to collect information from volunteers or available well logs on the wells used by the respondents. The CDC should collect information on the construction, age, depth, and location of the well relative to important land use activities. The study overall will be better served by gathering data on these important variables that can impact the risks associated with drinking well water. Other means of exposure: The survey design should account for other potential sources' contaminants detected in the samples provided by respondents. CLA urges the CDC to design the survey questions to account for other means of exposure to contaminants, such as workplace hazards and diet. Length of study: The ICR indicates that the CDC will conduct up to ten investigations per year, and each will involve an average of 200 respondents, but does not specify the number of years the study will be conducted under this ICR. The CDC should clarify whether some respondents will be tracked over a period of years, or whether all of the respondents will provide only a one-time sample. CLA appreciates the opportunity to provide these comments on the proposed ICR. CLA urges the CDC to consider these recommendations, and looks forward to reviewing the findings of the studies. Please contact Rebeckah Adcock, Senior Director	

		Government Relations, CropLife America, with any questions at radcock@croplifeamerica.org. Sincerely, Beau Greenwood Executive Vice President Government Relations & Public Affairs	
Email request	Erik Milito Group Director Upstream and Industry Operations 1220 L Street, NW Washington, DC 20005-4070 Telephone 202-682-8273 Fax 202-682-8426 Email militoe@api.org	May 10, 2016 Via E-Mail Leroy A. Richardson Information Review Collection Office Centers for Disease Control and Prevention 1600 Clifton Road, NE MS-D74 Atlanta, GA 30329 Re: Comments of the American Petroleum Institute (API) to the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) Proposed Data Collection Submitted for Public Comment and Recommendations on its Proposed Information Collection Plan, "Health Risks for Using Private Wells for Drinking Water" (81 Federal Register 12902) -- Docket ID Number CDC 2016 – 0027. The American Petroleum Institute (API) is a national trade association with more than 660 member companies and represents all sectors of America's oil and natural gas industry. Our industry supports 9.8 million American jobs and contributes $1.2 trillion in added value to the economy. Specific to our upstream members, operators strive for safe and environmentally responsible exploration and production of natural gas, crude oil, and associated liquids on lands administered by state and federal authorities. Concerns are addressed through the powerful combination of continually - improving industry practices, advancing state programs, and federal environmental statutes–all working together to provide an effective structure that allows for the essential development of the nation's oil and natural gas resources while protecting the environment. We read with interest the March 11, 2016 Federal Register notice announcing the Centers for Disease Control's (CDC's) request for information specific to its proposed information collection plan "Health Risks for Using Private Wells for Drinking Water" (81 Federal Register 12902). According to the U.S. Environmental Protection Agency (EPA), over 15 million	Steps taken by CDC in response to comments: Please note that this a Generic ICR Clearance, and the specifics of each study will be provided as they are developed. 1. CDC will use appropriate methods to identify and recruit an unbiased sample of study participants. 2. CDC will make every effort to incorporate existing data about wells and well water quality when designing studies to be done under this generic ICR. 3. See 2, above. 4. We will assess other potential sources of exposure to contaminants of interest in private well water. 5. We will work with our public health partners to determine the public health response to our study findings. CDC does not have authority to develop regulations about water quality. 6. OMB forbids collection of health data for these purposes. 7. CDC will ensure that all biological specimens and environmental samples will be properly collected, stored, shipped, and analyzed. Attachment 1. 1. The information provided in this FRN is limited on some points as it is intended to be a Generic ICR Clearance

		U.S. households (approximately 15 percent of Americans) rely on private water wells for drinking water. While EPA does regulate public water systems, through the Safe Drinking Water Act (SDWA), EPA does not have the authority to regulate private drinking water wells. The protection and maintenance of a private water well is primarily left to the responsibility of the homeowner. However, certain aspects are permitted and regulated by state and local authorities. For example, South Carolina requires that its Department of Health and Environmental Control be notified prior to private water well construction and the well be constructed according to state standards. Similarly, in Colorado, a new private water well that diverts ground water must have a well permit; obtained by filing an application with the State Engineer. Finally, states have varying requirements on testing and maintenance of a private water well before a property transaction can be initiated and concluded. Erik Milito Group Director Upstream and Industry Operations 1220 L Street, NW Washington, DC 20005-4070 Telephone 202-682-8273 Fax 202-682-8426 Email militoe@api.org Mr. Leroy A. Richardson May 10, 2016 Page Two Organizations such as the National Groundwater Association (NGWA) and the National Association of County and City Health Officials (NACCHO) offer private well owners pertinent information on well protection, maintenance, and well water quality (see http://www.wellowner.org/water-treatment/ and http://www.naccho.org/programs/environmental-health). API strongly urges the CDC to considering partnering with NGWA, NACCHO, and other state organizations as it moves forward with its investigative plan and tool development. Much of the critical initial data that the CDC needs for ground truthing its investigation may already be available. Regarding industry's part in groundwater protection, API members recognize that the key to protecting groundwater during our operations is proper oil and natural gas well	rather than an ICR for a specific study. 2. The characterization noted in our ICR is characterization of exposures, not demographics. 3. Investigations could be precipitated a number of ways, including following up on new findings of specific contaminants is wells in a specific geographic area, or providing assistance to our public health partners with a specific interest in a well water contaminant. CDC anticipates that there will only be one request at a time. NCEH cannot sponsor studies requested by an individual or group of individuals. The studies are limited to exposure assessment, no health outcomes will be included. CDC responded to requests for additional information by sending the information via email (Stephanie, I thought I remembered that you did this, but I can't find the email). Our public health partners will determine if the local community will be included in the data collection instrument development. 4. OMB may or may not approve multiple data collections in one area. 5. CDC has clarified that this is an example. The number of individuals recruited per household will depend on the goals of the study as developed by CDC and public health partners. CDC typically does not collect data on non-participants. However, if this is of interest to our public health partner, we could do that. CDC will recruit study participants as

		construction. We have developed detailed standards for this based on field experience and significant advances in drilling and construction techniques. A typical natural gas well uses three million pounds of steel and cement. The redundant layers of cement and steel casing are designed to protect potable groundwater resources, which are normally located within the first several hundred feet below the ground surface. The oil and natural gas industry typically targets formations that are thousands of feet below the surface to reach the resource-bearing formations. A properly designed oil and natural gas well is paramount to successful industry operations and protecting water resources for nearby landowners. Moreover, a properly designed, installed, and maintained private water well is equally important to supply safe potable water to the homeowner. The industry has an interest in the scope and outcome of the proposed ICR and final plan, because we are careful stewards of ground water resources in the basins in which we operate. We have several general questions (not an exhaustive list) that we ask the CDC to address with regard to its proposal in the Federal Register. Our primary concern is the obvious lack of detail provided in the actual Notice, regarding a tremendous number of variables which are sure to affect the outcome of the investigation. In addition, we have provided more detailed comments on the information collection plan and accompanying documents (see Attachment 1). These documents were requested of the CDC, but unfortunately were not provided as part of the Federal Register Notice or included as "Supporting Documents" in docket CDC 2016 – 0027. Overall, our comments are intended to promote enhancements to the quality of the study approach, its utility, clarity, and accuracy. Specifically, we ask the CDC to: 1. Develop specific and appropriate selection criteria to ensure there is no bias from homeowners when choosing a population of private water wells for the investigation. Due to the random nature of its selection criteria, EPA had difficulty with the public nomination process for locations in conducting the retrospective case studies as part of the "Study of the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources." 2. Indicate how it will consider the geology/hydrogeology where the selected private water wells exist and how will the	many ways as possible. 6. This is a Generic ICR Clearance, and the details of individual studies are not included. Details about sampling frame, water testing protocols, etc. will be specified for each study. CDC will work with laboratories to ensure that data from private well water analyses are kept private and confidentialy. Names, addresses, and other PII that might appear on data forms would be redacted in case of a FOIA. 7. We will consider your comments when developing the questionnaires to be used in the study. The sample provided is just to indicate the types of questions we may ask. 8. Our Office of Science has a protocol in place to determine whether IRB review is required. They ruled that IRB review is not required. Study results will be shared with participants in ways determined by CDC and public health partners, but may include a letter with a phone number to call if there are questions, or an in-person community meeting where people will get only their results and can discuss them with a public health official. 9. Specific methods for data analysis will be determined for each individual study. The overall intent of these investigations is to assess potential exposures from household wells. Specific details will depend on the study. Confounders will be selected based on community characteristics and the

		formations, water use, and land use of the area be considered in understanding the baseline of the water well quality. This is particularly important in regions of the west where flood irrigation has been used for decades, which undoubtedly impacts shallow private water wells. 3. Determine how baseline water quality work will be undertaken to understand the aquifer and naturally occurring chemical and biological constituents versus what might be attributed to historical or current land uses. Mr. Leroy A. Richardson May 10, 2016 Page Three 4. Determine how the implication of positive/negative urine and blood samples be attributed to water rather than other causes, such as poor housekeeping near a private water well (storing of chemicals, oil, debris, etc.), the location of a well near a septic system, or the ingestion of other products by the participant. 5. Develop a response plan should a "contaminant" be found above some health limit and communicate the health limit selected to serve as the baseline. 6. Determine the anticipated baseline work with respondents to understand individuals' health conditions before the sampling begins. People with existing health conditions, with concerns about their water, are more likely to be participants potentially resulting in a biased outcome. 7. Ensure that: i) proper protocols are followed as respondents receive and return blood and urine kits and samples, ii) the respondent is actually the provider of the samples, and iii) extraneous substances are not introduced to the samples. Overall, API reminds the CDC that any sampling event would be nothing more than a "snapshot in time," which may or may not be representative of the normal conditions for the location of the private water well in question. Before embarking on this effort we encourage the CDC to review data sets that already exist (i.e., potable groundwater sampling completed by the industry in Pennsylvania associated with "pre-drill" activity). There are additional data sets available that should be evaluated prior to initiating a new research effort. We would be happy to discuss these issues with you further. Please contact Stephanie Meadows of my staff (202-682-8578	contaminant(s) of concern. Data ownership will be determined for each study separately. If CDC owns the data or supported data collection, and other criteria are met (e.g., sufficient sample size) , the data will be made publically available. 10. CDC has no role in regulating water quality. Research as a specific meaning as determined by our Office of Science.

		or meadows@api.org), if you have questions regarding our submittal or if you would like to arrange a small group discussion. Again, we suggest that the agency partner with state organizations that are best positioned to assist with the varying state and local requirements for private wells and provide existing data. Sincerely, Erik Milito Group Director Upstream and Industry Operations American Petroleum Institute Attachment Attachment 1 Detailed Comments and Questions of the American Petroleum Institute (API) on the CDC Collection Plan and Instruments (81 Federal Register 12902; March 11, 2016) 1. General The information provided in the six documents reviewed is limited, vague, non-specific and lacking in scientific rigor. The methodological details provided are not sufficient to fully understand and evaluate what they intend to do and how it will be done. As such, key characteristics of programmatic quality, objectivity and transparency are a leap of faith. Specific concerns are addressed below, which are organized thematically, rather than by document (although several documents are specifically referenced as examples). 2. Goal and Justification Form A Justification states that these investigations "are needed to characterize the populations' drinking water from private wells in specific regions of the country." The US Census Bureau's American Housing Survey (AHS) already provides this information and is considered "the most comprehensive housing survey in the US, with the same units interviewed since 1985." Moreover, the sampling regimens/frames are of the highest design quality. The AHS provides regional results, so perhaps the CDC's National Center for Environmental Health (NCEH) should peruse this data source to see if that need is already fulfilled in a more scientific manner than what they propose in their Generic Clearance proposal. The utility of these data to address the goal of informing	

		public health measures and reducing health burden related to drinking water from private water wells are questioned, with the value determined by the nature of the health burden under consideration. Although these proposed field experiments could have value in the context of an epidemic scenario, the design and methods are unlikely to be sufficiently rigorous and appropriate for chronic and/or non-specific (i.e. rash, head ache) types of illness. The documents provided by CDC/NCEH do not demonstrate how the data will effectively inform public health decision making. 3. Process for Initiating, Selecting and Prioritizing Investigations It is not clear what precipitates an “investigation.” It appears that an investigation is prompted by a “requesting agency” or some other local authority/jurisdiction, but the specifics of that process (e.g. eligibility criteria, how to initiate the request, etc.) are not described. Ordering of events was particularly unclear: Do the jurisdictions request assistance in these investigations based on their own assessments? Or, does CDC/NCEH choose a region/town/community to investigate and then inform the local health agency that a problem exists? Is it a mix of the two, with jurisdictions requesting investigations, but CDC/NCEH also able to independently collect data that can be either stored for potential future requests by local authorities or examined and published immediately by CDC/NCEH? Is a requesting agency required to initiate data collection? Can CDC/NCEH be engaged by an individual or group of citizens (or an NGO) concerned about private well water – or who would like free water testing? What is necessary and sufficient to initiate an investigation? What are eligibility criteria for selecting jurisdictions for investigation? How are multiple requests prioritized? What are the criteria for prioritizing (will communities living near hydraulic fracturing operations receive a higher priority than those living near farms or other industrial sites)? How many investigations can be conducted simultaneously? Attachment “D” (GenIC request form) was not attached as stated in Form Part B, which may possibly assist in understanding the process and eligibility criteria for communities/locales requesting assistance. This, in addition to other Appendices referenced within documents, but which	

		were not attached, was requested, but there was no response. ▯ As the CDC states, each individual investigation will be different and subject to the needs of/tailored to the individual locale/jurisdiction, will there be individual protocols developed and available for the local community to view and comment? 4. Time Frame ▯ Plans indicate (Justification Form A, pg. 9) that each investigation will entail a one-time information collection. Ideally, the candidate communities would be identified on a yearly basis to afford an opportunity for researchers to collect additional well water samples for differentiation among potential sources of contaminants of interest or in the natural fluctuation of groundwater and consequently the resulting concentration of constituents present in the groundwater. 5. Recruitment/Selection of Households and Private Wells ▯ See Section 3 above for selection/identification issues with respect to locales/communities. ▯ What was the basis for determining that 200 is a sufficient sample size, regardless of geographic region and total population? For particularly heterogeneous environmental conditions and/or demographic composition, 200 could be less than necessary/optimal to generate valid and robust findings. ▯ Part B, page 5 describes different approaches for subject selection and recruitment based on the size of the underlying population being investigated. However, methods are only described for (1) populations 200 or less, (2) populations between 200 and 500, (3) "Well Events" or (4) Owner Organizations. Does that mean that populations over 500 will be recruited via options 3 or 4? Or does it mean that populations over 500 will not be eligible for private water well investigations? Or does it mean something else? If populations over 500 are eligible, but will not be recruited via options 3 and 4, these methods are missing. ▯ The sampling strategy suggests, as described above (but is not explicit) that one individual per household will be included in the investigation. That is, well water data will be at the household level, but only one person will provide biological sample(s) and answer the questionnaire. How will that individual be selected? Head of household (likely to over or under estimate one gender over another based on geographic region)? Oldest in the family or random selection of anyone	

		over the age of 18? Will that respondent be directed to answer the questions based on their individual activity or the drinking patterns on average for the household? As with all convenience samples, the potential for bias due to self-selection of participation exists. This is a function of both the proportion and characteristics of those eligible who choose to participate. For the proposed investigation, recent media attention around drinking water quality, particularly for those near hydraulic fracturing operations, could lead to differential participation , with those nearer operations (or more aware of issues) and exhibiting symptoms of stress more likely to participate. Ideally, it would be very useful to know some (non-sensitive information) from those who choose not to participate – e.g. whether they have private testing done on their own. his may be an important indicator of awareness, socio economic status, or other aspect differentially related to participation. Recruitment methods may be improved by tailoring them to the study population, as well as by incorporating social media and/or the internet. 6. Well Water and Tap Water Sampling The overall body of this program lacks any specificity regarding the chemical analyses to be undertaken, laboratory qualification, or quality assurance/quality control guidance. Although it is likely CDC will require lab certification for participation in the program, it is not explicit in the plan. The analytical data collection, sampling and reporting are critical components in this investigation as the results could drive policy and regulatory actions. Consequently, the entire well sampling effort needs a robust peer review and oversight to ensure the samples are properly and consistently collected, the custody controls of those samples are in place, the laboratory analytical analysis are documented, and the reporting protocols are consistent across the entire sampling exercise. The CDC will need to work with each state regulatory agency to ensure a state certified laboratory is used for the effort. It may be that the Paper Reduction Act request does not require such specificity, but external review of the formal plan (including final versions of the questionnaire(s) as well as the specifics of lab recruitment) would help ensure that the best science is applied for the most representative results.	

		▯ Such a lab effort would also require stipulation as to how the data will be provided by the lab to the “requesting agency” as well as to the well/tap users – there can be an extra cost burden for the lab to generate property-specific/person-specific reports. Many property owners expect their results to be held as “confidential” in nature. How does the agency plan on providing those results to the property owner and protecting the rights of the property owner under a Freedom of Information Act (FOIA) request by external groups? Our experience has been that environmental labs typically issue a sample delivery group (SDG) report including up to 20 samples (useful for the agency) and may note individual reports required to maintain privacy as “amended.” This can raise some concern for the well user that there is something wrong with the data or something is being hidden, so it is preferable to have each individual analytical report intended for reporting to the well user issued without that notation. The lab would need to develop or implement a sample-specific reporting routine as well as the SDG routine for all the samples within a quality control (QC) group (i.e., represented by a set of QC blanks, duplicates, and standard run). Laboratories running clinical samples are more likely to issue individual reports. ▯ Regarding specific analytical concerns, the program does not describe what the specific analytes will be or what screening levels are likely to be used (notwithstanding “How Data Will Be Analyzed” in Supporting Statement A) to determine whether a concern is raised regarding potential exposure or (in the case of clinical samples) actual exposure. The well questionnaire does provide a list of analytes for which the respondent is to indicate whether the water has previously been measured; one might infer this is the list of chemicals of interest for the requested analysis – but it should be explicit in the plan, as should be technically and clinically justified screening levels. ▯ Given that the water samples will be collected, stored and shipped by (presumably untrained) homeowners, rather than trained personnel, raises immediate concerns about sample contamination and other errors/issues that could impact results if the instructions are misunderstood or simply not executed properly (e.g., the water was not run for at least a full three minutes before sample collection) by even the most well-intentioned homeowner.	

		▯ What effort has the CDC considered if a property owner's private water well is shown to have elevated concentrations of constituents? If a property owner has elevated concentrations they will likely request additional sampling or confirmation of the results. How does the CDC plan to manage stakeholder issues resulting from these efforts? The CDC needs to recognize that many property owners will not understand a lab report or how to interpret the results. Consequently, the CDC will be faced with a considerable challenge in managing the external stakeholders without a strong communications approach, tailored for stakeholders that clearly articulates the entire process. 7. Questionnaire ▯ The ordering and phrasing of questions (both of which are important because they impact the answers you will receive) suggest an unfamiliarity with survey design. The ordering of the questions is disorganized and somewhat confusing; the phrasing of questions is often leading or based on assumptions not made explicit in prior questions. In addition, questions should be designed to measure or operationalize a specific construct. Many do not (e.g. #38, #39). ▯ Personal sensitive information (race, age, income) should always be at the end of a questionnaire; other questions serve to "warm up" and not begin with age and income level. ▯ Age should be asked as date of birth. ▯ Suggest adding questions about the age of the house, the well and the piping – approximately what year was the house constructed? Were there any renovations done? If so, what year(s)? Is the well casing cemented? Is the wellhead above grade, below grade, at grade, or buried? When was the water well last serviced? What is the depth of the well? Are there treatment systems in use or previously used (i.e. water softerners). Are they on public sewer or septic? If septic, when was the last time it was pumped? ▯ Question #15 asks about both drinking and cooking habits in the past week. These should be separate questions, as they are different behaviors/activities and each is carried out differently by each member of the family. ▯ Question #16 assumes drinking water from other sources at home. There should be a prior question as to whether they drink from other sources at home.	

		▯ Question #27 is unclear as to the basis for this limited selection of health issues; also, this question is generally phrased as “have you ever been told by a medical professional, etc.” These questions exist in the literature (e.g. The National Health and Nutrition Examination Survey or NHANES) and should be used to facilitate comparisons. ▯ Question #29 lists three possible health concerns (1) gastrointestinal (GI) illness, which could be anything from Gastroesophageal Reflux Disease (GERD) to Inflammatory Bowel Disease (IBD) to constipation. It is much too broad to be informative, (2) headaches – a highly non-specific symptom that could indicate anything from a brain tumor to tension and (3) Cancer – another highly broad and uninformative category. Finally, “other” is also an option. With three options in which headaches are followed by cancer, it is not clear why these very broad, self-reported, unconfirmed health endpoints were chosen, how they will be used in the analysis and what information they will add to the investigation. 8. Ethics Review and Consent ▯ In Part A Justification, on page 13, CDC states that because their proposed activity does not meet the criteria of “generalizability” as outlined in the Federal Protection of Human Subjects (45 CFR 46) it is exempt from ethics review. This determination is not made by the entity proposing an activity that involves human participants and it is not clear if an internal review board made this determination or if CDC staff determined this on their own. ▯ It is debatable whether this activity would not be considered generalizable. However, what is more important is protecting participants from risk and harm and having one’s activity reviewed to reduce the potential for harm and maximize the benefits derived from participation. It seems clear this effort would benefit from such as review, particularly given the limited description of site and subject selection, the sensitive nature of some of the questions in the survey and the procurement of biological samples. ▯ Another consideration is sharing testing results with the study participant. How will these results be communicated? How will questions be addressed and by whom? How will these results be placed into context? ▯ There seem to be plans for communication – who is	

		responsible for ensuring dissemination of findings, the locale or CDC? The consent form is referenced in the Part A Justification document, and was specifically requested from CDC, but was not received for review and comment. The documents do not describe how and when CDC will obtain consent. 9. Data Analysis, Storage, Ownership What analyses are planned? The Statistical Methods Form B states on page 7 that data analysis will be largely descriptive. What methods do they intend to use? Although descriptive analyses are consistent with CDC's statement that concentrations obtained from water and urine samples will be compared with national data such as NHANES it is not consistent with the type of data that CDC is collecting on the questionnaire (e.g. health outcomes). These data suggests that CDC sees the potential for more detailed, associational analyses to be conducted that could include hypothesis testing and effect estimation tantamount to a formal epidemiologic study, for which the proposed investigative design, methods and subject selection are not appropriate. The disconnect between the design and methods with the data collected and potential analysis raises serious concerns about the intent of these investigations. What is the basis for confounder selection? How will they be incorporated into the analysis that is strictly descriptive? How would they be used to determine risk? Is a formal risk assessment planned? If so, what methods will they use? Who owns the data? That is not clear. Both local jurisdictions and CDC/NCEH will store the questionnaire data (but only jurisdictions will keep the water and biological samples for unspecified periods of time). Given that FOIA is operational (page 13, Part A Justification); will the data be publically available? If so, what are the plans for the public to access this data? Will it be like NHANES? Can data be pooled from different investigations? 10. Potential for Epidemiologic Research Although CDC states in their proposal documentation that the data collected from individual investigations will be used strictly to design support programs for individual communities to improve the quality of private water wells rather than to	

		further regulate water quality or conduct research, there seems to be nothing to prevent these activities from taking place. See item 9 for additional comments on concerns for how that data can be used, etc	