DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day–15–0048; Docket No. ATSDR–2015–0006]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed extension of the information collection entitled ''ATSDR Exposure Investigations (EIs)'' (OMB Control No. 0923–0048, Expiration Date 5/31/2016). EIs are used by ATSDR as part of its Public Health Assessment (PHA) process to identify whether exposure to contaminants have occurred in communities and to make recommendations for how to lower or eliminate exposure.

DATES: Written comments must be received on or before November 30, 2015.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2015–0006 by any of the following methods:

- *Federal eRulemaking Portal: Regulation.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

ATSDR Exposure Investigations (EIs), (OMB Control No. 0923–0048, Expiration Date 5/31/2016)—Extension—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year extension of this generic clearance to allow the agency to conduct exposure investigations (EIs), through methods developed by ATSDR. After a chemical release or suspected release into the environment, EIs are usually requested by officials of a state health agency, county health departments, the Environmental Protection Agency (EPA), the general public, and ATSDR staff.

EI results are used by public health professionals, environmental risk managers, and other decision makers to determine if current conditions warrant intervention strategies to minimize or eliminate human exposure. For example, three of the EIs that ATSDR conducted in the past three years include the Colorado Smelter (CO—blood lead and urine arsenic), ASARCO Hayden Smelter Site (AZ—blood lead and urine arsenic), and Decatur (AL—perfluorochemicals [PFCs] in serum).

Example 1: Colorado Smelter Blood Lead and Urine Arsenic Sampling, CO

The site is a former smelter located in Pueblo, Colorado. Past sampling found elevated levels of lead and arsenic in residential soils and a slag pile associated with the smelter. ATSDR sampled blood lead levels (BLLs) in children and adults and found seven children that had BLLs near or exceeding the level of 5 micrograms per deciliter (mg/dL) (a level identified by ATSDR as a level of concern for lead effects in children). One adult had an elevated level of arsenic in their urine. Speciation of the sample determined that it was primarily organic arsenic, probably resulting from eating seafood.

- The local health department conducted a Healthy Homes Inspection for these families having children with elevated BLLs and ATSDR recommended that the children follow up with their primary care provider.
- On June 10, 2014, the local health department obtained a six year grant from the EPA Region 8 to conduct health education, BLL screening, assist in the coordination of developmental and cognitive evaluations in affected

children from a designated area of Pueblo, and conduct other public health actions/investigations as stipulated in the grant.

• On December 11, 2014, EPA listed the Colorado Smelter site on the National Priority List (NPL).

Example 2: ASARCO Hayden Smelter Site, AZ

The community is located in the vicinity of the ASARCO Hayden Smelter, which has been operating for 100 years as a copper ore processer. The processing has resulted in lead and arsenic contamination in the surrounding residential area and in tailing piles used for recreation. Limited sampling of the community in the past found elevated BLLs and arsenic in urine. Based on community concerns, EPA requested that ATSDR conduct an EI to assess potential exposure of the community to lead and arsenic.

• In April, 2015, ATSDR collected 83 BLL and 58 urine arsenic samples from the community.

• Participants have been notified of their results and the EI report is being prepared.

Example 3: Perfluorochemical Serum Sampling, Decatur, AL

Perfluorochemicals (PFC) are a class of organofluorine compounds that are used in a variety of industrial and consumer products including fire-fighting foams; personal care and cleaning products; and oil, stain, grease, and water repellent coatings. These coatings are used on carpet, textiles, leather, ''non-stick'' cookware, and paper wrappers used on fast food items. As a result, United States (U.S.) general population exposure to PFCs is common.

In 2007, PFCs were released by a chemical manufacturer near Decatur, AL, and impacted environmental media in the area. In 2010, ATSDR conducted an EI to assess exposure of residents to PFCs in blood. PFCs were found in the serum of people that regularly used the public water system in the area as their primary drinking water source.

Recommendations of the EI included continued monitoring for PFCs in the public water supply and continued biological PFC testing in the community to determine if PFCs in the community had been reduced.

Based on the results of the 2010 EI, ATSDR is preparing to conduct another EI at the site in 2016 (approved by OMB on 8/10/2015), including biological sampling of serum and urine to:

• Compare individuals' current serum PFC concentrations with their 2010 serum PFC concentrations.

• Compare individuals' serum PFC concentrations to the national population reference values (NHANES 2011–2012).

• Calculate the biological half-life for each PFC species using paired blood and urine PFC concentrations to improve the understanding of the pharmacokinetic behavior of these compounds in humans.

• Evaluate the potential existence of non-drinking water PFC exposure pathways through physiologically-based pharmacokinetic (PBPK) modeling.

All of ATSDR's targeted biological assessments (*e.g.,* urine, blood) and some of the environmental investigations (*e.g.,* air, water, soil, or food sampling) involve participants to determine whether they are or have been exposed to unusual levels of pollutants at specific locations (*e.g.,* where people live, spend leisure time, or anywhere they might come into contact with contaminants under investigation).

Questionnaires, appropriate to the specific contaminant, are generally needed in about half of the EIs (at most approximately 12 per year) to assist in interpreting the biological or environmental sampling results. ATSDR collects contact information (*e.g.,* name, address, phone number) to provide the participant with their individual results. ATSDR also collects information on other possible confounding sources of chemical(s) exposure such as medicines taken, foods eaten, hobbies, jobs, etc. In addition, ATSDR asks questions on recreational or occupational activities that could increase a participant's exposure potential. That information represents an individual's exposure history.

The number of questions can vary depending on the number of chemicals being investigated, the route of exposure (*e.g.,* breathing, eating, touching), and number of other sources of the chemical(s) (*e.g.,* products used, jobs). We use approximately 12–20 questions about the pertinent environmental exposures per investigation.

Typically, the number of participants in an individual EI ranges from 10 to 100. Participation is completely voluntary, and there are no costs to participants other than their time. Based on a maximum of 12 EIs per year and 100 participants each, the estimated annualized burden hours are 600.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Exposure Investigation Participants	Chemical Exposure Questions	1,200	1	30/60	600
Total					600

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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