DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day–19–18AJK]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled ''Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs)'' to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on July 19, 2018 to obtain comments from the public and affected agencies. ATSDR received eight comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs)—New—Agency for Toxic Substances and Disease Registry and the National Center for Environmental Health (ATSDR/NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Per- and polyfluoroalkyl substances (PFAS) are a large group of man-made chemicals that have been used in industry and consumer products worldwide since the 1950s. Although some PFAS are no longer produced in the United States, they many remain in the environment and may impact people's health. Thus, PFAS are contaminants that have gained national prominence over the last decade.

Under Section 8006 of the Consolidated Appropriations Act, 2018, the Agency for Toxic Substances and Disease Registry and CDC National Center for Environmental Health (ATSDR/NCEH) are requesting a three-year Paperwork Reduction Act clearance for a new information collection request (ICR). ATSDR/NCEH will conduct exposure assessments (EAs) at current or former domestic military installations known to have PFAS in drinking water, groundwater, or any other sources of water. The annualized number of EAs assumes the following. ATSDR/NCEH will conduct a minimum of eight EAs, but ATSDR/NCEH may complete an additional seven for a total of 15 EAs. Therefore, ATSDR/NCEH anticipates conducting five PFAS EAs each year for three years.

Public health professionals, environmental risk managers, and other decision makers can use EA results to make informed decisions about the sources and impact of PFAS contamination in environmental media within their own community and jurisdiction. The data will support their recommendations for public health actions to reduce or eliminate harmful levels of PFAS in the local environment. These EAs are not intended to yield information about PFAS exposure that will be generalized beyond the defined boundaries of each investigation; however, ATSDR/NCEH will also use these EA findings to inform a future national PFAS health study.

Community Event Evaluation Survey: ATSDR/NCEH will hold a public meeting prior to the start of the EA at each EA location. A Community Event Evaluation Survey will be used as a way for the EA team to receive feedback from prospective EA participants about ATSDR's PFAS public health messaging, the enrollment process and to gauge local feelings toward the ATSDR PFAS EA project. It is assumed that approximately 250 community members will attend the public meeting that will be held to inform the community about the EA effort. Using a response rate of 65 percent, it is assumed that 163 community members will fill out the community event evaluation survey at each EA location and the survey will take approximately 5 minutes (815 members for 5 EAs). The resultant time burden is 68 hours annually for 5 EAs.

Household Eligibility Screener: ATSDR/NCEH will recruit a desired sample size of 379 respondents per EA (1,895 total per year) using statistical household sampling methods. Eligibility criteria for individuals include specific age intervals (*i.e.,* children older than three years given the lack of NHANES comparison data for younger children), lack of bleeding disorders that would prevent a blood draw, and time of residency (*i.e.,* at least one year in the home).

Applying an average U.S. household size of 2.5 members, per EA, ATSDR/NCEH will enroll respondents from 152 eligible households (379/2.5). To identify the 152 eligible households, we further assume a 65 percent household eligibility rate. This will require administering a 5-minute household eligibility phone script to 234 heads-of-households per EA (152 * 100/65), or to 1,170 heads-of-households per year (234 × 5). The annual time burden requested for eligibility screening is 98 hours.

Consents: All eligible respondents will be consented before being included in each EA. The consent forms will include adult consent, and parental permission and child assent forms, as appropriate. Each consented respondent will provide a serum and a urine sample. In addition, heads of households from ten percent of households using tap water for their drinking water will consent to provide tap water and indoor dust samples. The consent forms will include permission to store some biospecimens and environmental samples for future analysis and will include permission to recontact respondents for potential investigations or studies in the future. ATSDR will also collect contact information to provide respondents with their individual sampling results. The time associated with administering the consent forms is approximately 10 minutes for 1,440 adults (240 hours); 10 minutes for 455 parents providing permission for their children aged 3–17

years old (76 hours); and 10 minutes for 191 children aged 12–17 years old who assent for themselves (32 hours).

Exposure Assessment Questionnaires for Biological and Environmental Testing for Adults, Parents, or Children: ATSDR/NCEH will administer an exposure questionnaire to all consented respondents that includes questions associated with potential exposure to PFAS both inside and outside the home (*e.g.,* work or school). The adult questionnaire also includes several questions associated with water use and flooring type while the child questionnaire includes questions regarding playing in soil; these questions are intended to evaluate potential exposure and to support the environmental testing. The time associated with administering the questionnaire and completing the biological sampling is approximately 30 minutes for 1,440 adults (720 hours); 15 minutes for 264 parents responding for their children, 3–11 years old (66 hours); and 15 minutes for 191 children, 12–17 years old, who respond for themselves (48 hours).

Household Recruitment Script for Environmental Sampling: The households providing environmental samples (tap water and indoor dust) will be a random 10 percent subset of households that report using tap water for drinking water. Assuming a 65 percent response rate, ATSDR/NCEH will administer a five-minute recruitment script to 23 heads-of households who are eligible to take part in each EA (152/10 * 100/65). This will result in annual recruitment from 117 heads-of-households and 10 hours for five EAs.

Consent for Environmental Testing: ATSDR/NCEH will consent a 10 percent subset of households deemed eligible for the EA for testing of tap water and indoor dust samples; therefore, the desired number of households is 15 per EA, or 76 per year (152 * 10/100 * 5). The time associated with consenting to the environmental sampling is 10 minutes, resulting in a burden of 13 hours annually for five EAs.

Environmental Sample Collection Form: ATSDR will collect samples from approximately 15 households per EA or 76 households annually (152*10/100*5) and fill out a sample collection form. The average time burden is estimated as 15 minutes per response for the sample collection forms (19 hours annually).

ATSDR estimates the total annualized time burden is 1,390 hours. Participation is voluntary, and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
EA Community Members	Community Event Evaluation Survey	815	1	5/60
EA Adults	Household Eligibility Screener	1,170	1	5/60
	Consent	1,440	1	10/60
	Exposure Questionnaire (Adult)for Biological and Environmental Testing.	1,440	1	30/60
EA Parents	Parental Permission	455	1	10/60
	Exposure Questionnaire (Child)for Biological Testing (Parent Proxy).	264	1	15/60
EA Children	Assent	191	1	10/60
	Exposure Questionnaire (Child)for Biological Testing (Child completed).	191	1	15/60
EA Heads-of-Households	Household Recruitment Script for Environmental Sampling	117	1	5/60
	Environmental Sampling Consent Form	76	1	10/60
	Environmental Sample Collection Form	76	1	15/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–19BN; Docket No. CDC–2018–0104]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ''Emergency Cruise Ship Outbreak Investigations (CSOIs)''. The purpose of this study is to allow the CDC Vessel Sanitation Program (VSP) to prevent the introduction, transmission, or spread of acute gastroenteritis (AGE) via cruise ships entering the United States from foreign countries.

DATES: CDC must receive written comments on or before January 28, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0104 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, 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. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.