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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day-22-0059; Docket No. ATSDR-2021-0008]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), 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 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 Per-or-Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs). This Revision information collection request (ICR) will allow ATSDR/NCEH to continue to conduct additional Exposure Assessments (EAs) that may be requested at military or non-military installations.

DATES: ATSDR must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2021-0008 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, N.E., MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR 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.

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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

Proposed Project

Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs) (OMB Control No. 0923-0059, Exp. 06/30/2022) – Revision - Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

Per-or-polyfluoroalkyl substances (PFAS) are contaminants that have gained national prominence over the last decade. 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, many remain in the environment and may impact people's health.

The Agency for Toxic Substances and Disease Registry (ATSDR) and the National Center for Environmental Health (NCEH) are requesting a three-year revision information collection request (ICR) to continue to conduct PFAS exposure assessments (EAs) at both military or non-military locations known to have PFAS in drinking water, groundwater, or any other sources of water. Previously, ATSDR was approved to conduct up to five EAs per year, for which the agency completed a total of eight. Currently, ATSDR is seeking approval to conduct up to three EAs per year for a maximum of seven additional locations.

Originally authorized under the National Defense Authorization Act (NDAA) of 2018, ATSDR is also mandated under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the "Superfund" Act, as amended by the Superfund Amendments and

Reauthorization Act (SARA) of 1986, to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances in the environment. NCEH can conduct EAs under the authority of Section 301 of the Public Health Service Act (42 U.S.C. 241).

The PFAS EAs are conducted using statistical sampling to produce unbiased estimates of exposure to PFAS in communities living on or near the chosen current or former military installations. The number of respondents per EA will vary, but we expect the number to be approximately 395, and to be determined by specific statistical methods.

The time burden associated with the EAs include the following collections:

- Community Event Evaluation Survey: ATSDR/NCEH will hold a public meeting prior to the start of the EA and attendees will be asked to complete a five minute Community Event Evaluation Survey. It is assumed that 163 of the 250 attendees will complete the survey at each EA site, resulting in a burden of 41 hours for three EAs.
- Household Eligibility Screener: ATSDR/NCEH anticipates asking approximately 269 adults in each household at each EA site to complete a five minute telephone script, resulting in a burden of 66 hours for three EAs.
- Estimation of Number of EA Respondents by Age Group: Based on the criteria in the Household Recruitment Phone Script,

149 households are assumed to provide the target sample size of 395 respondents at each EA site, with a total of 1,185 respondents for three EAs. Based on 2017 Census estimates of average household size (2.5), and number of adults (1.9), and children under 18 years of age (0.6) in the household, we are able to estimate the annual number of respondents by age group as the following for three EAs: 900 adults ≥18 years and 284 children (165 aged 3-11 years and 119 aged 12-17 years).

- Biological Testing Tracking: All of the EAs use biological sampling for PFAS (blood and urine). A biological testing tracking form for the testing event will be provided to ensure that all appropriate forms are completed and all biological samples are collected. The testing will take 20 minutes, resulting in a burden of 395 hours annually for three EAs.

- Adult Consent for Biological Testing: 300 adults at each EA site will be administered a 10-minute consent form for testing of blood and urine for PFAS, resulting in a burden of 150 hours annually for three EAs.

- Parental Permission Form for Biological Testing: A parental permission form will be administered to the parents of 284 children aged 3-17 years for testing of blood and urine.

The parental permission form will take 10 minutes resulting in a burden of 47 hours annually for three EAs.

- Child Assent Form for Biological Testing: Children aged 12-17 years (119) will assent to the testing of blood and urine for PFAS. The child assent form will take approximately 10 minutes, resulting in a burden of 20 hours annually for three EAs.

- Adult Exposure Questionnaire for Biological and Environmental Testing: 300 adults at each EA site will be administered an exposure questionnaire. The time associated with administering the questionnaire and completing the biological sampling is approximately 30 minutes, resulting in a burden of 450 hours annually for three EAs.

- Parent Proxy for Child Exposure Questionnaire for Biological Testing: 165 parents will respond to the 15-minute questionnaire for their children, 3-11 years, resulting in a burden of 41 hours annually for three EAs.

- Child Exposure Questionnaire for Biological Testing: Annually, 119 children will respond to the 15-minute child questionnaire for themselves (age 12-17 years), resulting in a burden of 30 hours annually for three EAs.

- Household Recruitment Script for Environmental Testing: ATSDR/NCEH will administer a five minute environmental recruitment script to 69 heads of households, resulting in a burden of six hours annually for three EAs.

- Consent for Environmental Testing: ATSDR/NCEH will obtain consent to test 10% of EA households for tap water and indoor dust samples using a 10-minute consent form for an annual total of 45 households, resulting in burden of eight hours annually for three EAs.

  Environmental Sample Collection: ATSDR/NCEH will complete sampling at 45 households for three EAs deemed eligible for the EA for testing of tap water and indoor dust samples. The sampling will take 30 minutes, for an estimated burden of 23 hours annually for three EAs.

ATSDR estimates the annualized time burden is 1,277 hours. Participation is voluntary, and there are no costs to participants other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
EA Community Members	Community Event Evaluation Survey	489	1	5/60	41
EA Participants (all ages)	Biological Testing Tracking	1,185	1	20/60	395
EA Adults	Household Eligibility Screener	807	1	5/60	66
	Consent	900	1	10/60	150
	Exposure Questionnaire (Adult) for Biological	900	1	30/60	450

	and Environmental Testing				
EA Parents	Parental Permission	284	1	10/60	47
	Exposure Questionnaire (Child) for Biological Testing (Parent Proxy)	165	1	15/60	41
EA Children	Assent	119	1	10/60	20
	Exposure Questionnaire (Child) for Biological Testing (Child completed)	119	1	15/60	30
EA Heads-of-Households	Household Recruitment Script for Environmental Sampling	69	1	5/60	6
	Environmental Sampling Consent Form	45	1	10/60	8
	Environmental Sample Collection Form	45	1	30/60	23
Total					1,277

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