



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day-17-17IY]

[Docket No. ATSDR-2016-0007]

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 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 "Biomonitoring of Great Lakes Populations Program III." The purpose of the proposed study is to evaluate body burden levels of priority contaminants in Great Lakes residents, particularly those who are at high exposure risk, in the Milwaukee Bay Estuary Area of

Concern (AOC) area that was not previously addressed in ATSDR's previous biomonitoring programs around the Great Lakes.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2016-0007 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., 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, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; 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 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

Biomonitoring of Great Lakes Populations Program III - New - 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 Paperwork Reduction Act (PRA) clearance for a new information collection request (ICR) titled "Biomonitoring of Great Lakes Populations Program III." ATSDR awarded funds to the Wisconsin Department of Health Services (WIDHS) to conduct this information collection under cooperative agreement #NU61TS000269-01-00. The purpose of the current program is to evaluate body burden levels of legacy and emerging contaminants in susceptible Great Lakes populations in the Milwaukee Estuary Area of Concern (AOC) in Wisconsin, an area that has not been previously covered by other Great Lakes initiatives.

The Great Lakes Basin has suffered decades of pollution and ecosystem damage. Many chemicals persist in Great Lakes waters and sediments, as well as in wildlife. These chemicals can build up in the aquatic food chain, and eating contaminated fish is a known route of human exposure.

In 2009, the Great Lakes Restoration Initiative (GLRI) was enacted by Public Law 111-88 to make restoration and protection of the Great Lakes a national priority. The GLRI is led by the U.S. Environmental Protection Agency (US EPA). Under a 2015 interagency agreement with the US EPA, ATSDR initiated the

Biomonitoring of Great Lakes Populations Program III program. This project will provide additional public health information to supplement the previous cooperative agreement programs CDC-RFA-TS10-1001 "Biomonitoring of Great Lakes Populations" (hereafter referred to as "Program I," OMB Control Number 0923-0044) and CDC-RFA-TS13-1302 "Biomonitoring of Great Lakes Populations-II" (hereafter referred to as "Program II," OMB Control Number 0923-0052) initiated in FY2010 and FY2013, respectively.

WIDHS received funding for the current program. WIDHS will recruit and enroll two subpopulations of adults in the Milwaukee Bay Estuary Area of Concern (AOC) who are known to eat fish from the Milwaukee River Basin and Lake Michigan. This study will not include pregnant women.

The target populations are: (1) licensed anglers living in proximity to the Milwaukee Estuary AOC and (2) Burmese refugees who are known to eat a substantial amount of fish from this area. WIDHS study staff will work closely with local refugee and citizen support organizations on participant recruitment.

The aims of the information collection in this surveillance project are:

1. Assess levels of contaminants (metals, polychlorinated biphenyls, chlorinated pesticides, perfluorinated compounds, and polyaromatic hydrocarbons) in blood and

urine of residents who consume fish from contaminated areas that had not been studied in previous Programs I and II;

2. Use the project findings to inform public health officials and offer guidance on public health actions to reduce exposure to Great Lakes contaminants.

This applied public health program aims to measure contaminants in biological samples (blood, urine and hair) from people who may be at high risk of chemical exposure in the Great Lakes area. These measurements will provide a baseline for current and future restoration activities. The results will be compared to available national estimates, such as those reported by the National Health and Nutrition Examination Survey (NHANES).

Respondents will be screened for eligibility and consent will be obtained. Participants who consent will respond to a questionnaire and participate in clinic visits for body measurements and biological specimen collection (blood, urine, and hair). Their blood will be tested for polychlorinated biphenyls, metals, perfluorinated compounds, persistent pesticides, and lipids. Urine will be tested for polycyclic aromatic hydrocarbons and creatinine. The hair samples (optional) will be saved for a later analysis.

Respondents will also be interviewed. They will be asked about demographic and lifestyle factors, hobbies, health

conditions that may affect fish consumption and fishing habits, and types of jobs which can contribute to chemical exposure. Some dietary questions will be asked with a focus on consumption of Great Lakes fish.

Participation in the study is voluntary and there is no cost to respondents other than their time. The estimated annualized burden for the program averaged over the three-year study period is 231 hours among 166 respondents. There is no cost to respondents other than their time spent in the study.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden (in hours)
Licensed Anglers	Eligibility Screening Survey (paper)	156	1	5/60	13
	Eligibility Screening Survey (online)	28	1	5/60	2
	Study Questionnaire (paper)	58	1	30/60	29
	Study Questionnaire (online)	87	1	30/60	44
	Clinic Visit Checklist and Body Measurements	133	1	35/60	78
	Follow-up Survey	133	1	5/60	11
Burmese	Eligibility	42	1	5/60	4

Refugees	Screening Survey				
	Contact Information Form	33	1	5/60	3
	Study Questionnaire	33	1	40/60	22
	Clinic Visit Checklist and Body Measurements	33	1	35/60	19
	Network Size Questions	33	1	5/60	3
	Follow-up Survey	33	1	5/60	3
Total					231

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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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