

One Health Harmful Algal Bloom System (OHHABS)

NEW

September 1, 2015

Point of Contact:

Amy McMillen

auh1@cdc.gov

Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases
1600 Clifton Road, NE, Mailstop D76
Atlanta, GA 30333

Table of Contents

- Abstract
- A. Justification
 - 1. Circumstances Making Case Notification Necessary
 - 2. Purpose and Use of Submitted Information
 - 3. Use of Improved Information Technology and Burden Reduction
 - 4. Efforts to Identify Duplication and Use of Similar Information
 - 5. Impact on Small Businesses or Other Small Entities
 - 6. Consequences of Less Frequent Case Notification
 - 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
 - 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
 - 9. Explanation of Any Payment or Gift to Respondents
 - 10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
 - 11. Institutional Review Board (IRB) and Justification for Sensitive Questions
 - 12. Estimates of Annualized Burden Hours and Costs
 - 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
 - 14. Annualized Cost to the Government
 - 15. Explanation for Program Changes or Adjustments
 - 16. Plans for Tabulation and Publication and Project Time Schedule
 - 17. Reason(s) Display of OMB Expiration Date is Inappropriate
 - 18. Exceptions to Certification for Paperwork Reduction Act Submissions

- [The goal of the One Health Harmful Algal Bloom System \(OHHABS\) is to collect data on harmful algal blooms \(HABs\) and human and animal illnesses related to HAB exposures.](#)
- [Data collected in OHHABS will be accessible to state health departments, federal partners and other stakeholders to better characterize HAB events and single human and animal illness related to HAB exposures and to inform future prevention efforts.](#)
- [Data will be collected electronically, with data accessible via the One Health Harmful Algal Bloom System \(OHHABS\), a web-based reporting system built on the same electronic platform as National Outbreak Reporting System \(NORS\) under OMB 0920-0004.](#)
- [Single cases of human and animal illness related to HAB exposures and environmental data about HABs will be voluntarily reported by state and territorial public health agencies.](#)
- [The data collected will be analyzed and presented through summaries and reports. Any communications or publications by CDC that arise from this collection will include a clear description of the reporting entities \(e.g., which states/territories voluntarily participate\) and a discussion of how their reporting and monitoring practices may differ.](#)

The Centers for Disease Control and Prevention (CDC) requests a three year approval for the [One Health Harmful Algal Bloom System \(OHHABS\) for harmful algal bloom \(HAB\) and HAB-related illness surveillance.](#)

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) is requesting 3 year approval for [surveillance activities through the One Health Harmful Algal Bloom System \(OHHABS\). Harmful Algal Bloom \(HAB\) surveillance activities were](#) previously covered under the Harmful Algal Bloom-related Illness Surveillance System (HABISS) OMB Control No. 0920-0004 through the National Center for Environmental Health (NCEH) but ceased due to defunding. [Currently, there are no HAB-related event or illness surveillance activities at CDC. NCEZID is now managing HAB-related event and illness surveillance; this surveillance is now a priority under NCEZID due to the Great Lakes Restoration Initiative.](#)

A. JUSTIFICATION

1. [Circumstances Making the Collection of Information Necessary](#)

Algal toxins from [Harmful Algal Blooms \(HABs\)](#) include some of the most potent natural chemicals; these toxins can contaminate surface water used for recreation and drinking, as well as food sources. HABs pose a threat to both humans and animals. Human and animal illnesses from environmental exposures to HABs in fresh and marine waters have been documented in the United States. Animal illness may be an indicator of bloom toxicity; thus, it is necessary to provide a One Health approach for reporting HAB-related illnesses and events.

[HABs](#) are an emerging public health concern. Several outbreaks related to HABs in freshwater settings have occurred in the United States. In 2009-2010, 11 HAB-related outbreaks in fresh water settings were reported to the CDC Waterborne Disease and Outbreak Surveillance System (WBDOSS). These 11 outbreaks represent 46% of the outbreaks associated with untreated recreational water reported in 2009-2010 and 79% of HAB-related outbreaks reported to WBDOSS since 1978. At least 61 persons experienced health effects such as dermatologic, gastrointestinal, respiratory, or neurologic symptoms. In August 2014, detectable levels of microcystin, a potent HAB toxin, were detected in drinking water supply in Toledo, Ohio, resulting in a “do not drink” water advisory and an extensive emergency response.

Known adverse health effects from HABs in marine waters include respiratory illness and seafood poisoning. In 2007, 15 persons were affected with respiratory illness from exposures to brevetoxins, an algal toxin, during a Florida red tide. From 2007-2011, HAB-related foodborne exposures were identified for 273 case reports of human illness through the former HABISS. Of these reports, 248 reported ciguatera fish poisoning or poisoning by other toxins in seafood, including saxitoxin and brevetoxin.

Domestic animal and wildlife HAB-related illnesses have also been documented in the United States. Between 2007 and 2011, 67 cases of canine intoxication related to HAB exposure were reported to CDC as part of a 5-year project that conducted enhanced surveillance for HABs and related illnesses in 10 states. Of the 67 canine cases, 87% of the cases reported exposure to fresh water and resulted in gastrointestinal illness, lethargy, neurological signs, or death. In 1998 a marine algal bloom along the Californian coast in Monterey Bay affected mussels, anchovies, sardines, birds, and sea lions. Over 400 sea lions died and displayed neurologic dysfunction due to poisoning of an algal toxin, domoic acid.

Factors that influence the occurrence of HABs include water temperature and nutrient levels. Warm waters with abundant phosphorus and nitrogen content (e.g., from urban or agricultural run-off) are more likely to form HABs. These conditions promote the growth of phytoplankton or algae that can produce toxins or otherwise cause illness in animals, people, and negatively impact the local ecology (e.g., reduced oxygen and light available for aquatic organisms) and economy (e.g., beach closures, shellfish bed closures). There is evidence that the frequency and geographic distribution of HABs is increasing as a consequence of climate change.

[OHHABS will be a centralized data source for public health surveillance of HAB events and HAB-related illnesses using a One Health approach that takes into consideration information from the environment, animal cases, and human cases. Outbreaks HAB-related human illnesses may already be reported to CDC by state and territorial public health agencies within the electronic National Outbreak Reporting System \(NORS\) under OMB 0920-0004. However, there is currently no national database for HAB events or single cases of HAB-related human or animal illness. A standardized data-collection system for HAB events and HAB-related illnesses is necessary to quantify and characterize HAB-related illnesses, refine event and case definitions, and inform One Health prevention efforts. To develop OHHABS, CDC has organized a voluntary HAB Working Group comprised of sixteen state and seven federal partners with expertise in HABs and illness surveillance. The HAB Working Group has drafted HAB event definitions and HAB-related human and animal illness case definitions to be used for information collected in OHHABS. The HAB Working Group also reviewed data elements used previously in HABISS and revised them to meet current surveillance objectives for OHHABS. CDC is authorized to collect this data under Section 301 of the Public Health Service Act \(42 U.S.C. 241\) \(Attachment A\).](#)

2. Purpose and Use of Information Collection

[The purpose of OHHABS is 1\) to provide a database for routine data collection at the state and national level to identify and characterize HAB events, HAB-related illnesses, and HAB-related exposures in the United States and 2\) to better inform and improve our understanding of HAB-related illnesses and exposures through routine surveillance to inform public health policy and illness prevention efforts. OHHABS \(electronic, year-round collection\) will include questions](#)

about HAB events and HAB-related illness for human and animal cases. OHHABS, a web-based reporting system, will be nationally available for state and territorial health departments to voluntarily report information about HAB-related human and animal cases and HAB events.

States and territories lacking a database to collect information on HAB events and HAB-related illnesses may use OHHABS as a repository to track and review HAB events and HAB-related illnesses within their state or territory. OHHABS data may help states and territories characterize the baseline frequency of HAB events and HAB-related illnesses. Data from states and territories will be assessed by CDC to determine and characterize HAB events and HAB-related illnesses nationally.

As with all routine public health surveillance conducted by CDC, participation by states and territorial health departments with OHHABS will be voluntary. Participating states and territories will be responsible for the collection and interpretation of these data elements at the state level and will voluntarily submit them to CDC. HAB event and HAB-related human and animal case definitions, created by the HAB Working Group, will be available online to assist states and territories. States and territories that lack state-specific case and event definitions may use the HAB-related human and animal case and HAB event definitions to identify suspect, probable, and confirmed HAB-related cases and HAB event, respectively, to report to OHHABS. The HAB-related human and animal case and HAB event definitions will also be used by CDC to assess data quality in OHHABS and to categorize events and cases for data dissemination (e.g., annual reports).

CDC will use the information provided by states and territories in OHHABS to identify and address knowledge gaps. This may include the improvement of existing case definitions for HAB events and HAB-related human and animal illnesses. OHHABS data will also help characterize temporal and spatial trends of HAB-related illnesses and health risks from HAB events, and will improve public health prevention and response in the United States. CDC will routinely assess the quality of, tabulate, analyze, and publish OHHABS data in surveillance summaries. Any communications or publications of data from OHHABS will include a clear description by CDC of the participating states and any differences in monitoring and reporting among the responding entities. The Great Lakes Restoration Initiative (GLRI) will use OHHABS data to inform and evaluate its work to restore and protect the Great Lakes ecosystem.

3. Use of Improved Information Technology and Burden Reduction

OHHABS is a web-based, password-protected reporting system built into the NORS platform hosted at CDC (ITSO/AHB), which supports reporting to CDC from state and territorial public health departments. NORS is a shared access point for foodborne and waterborne disease outbreaks and enteric disease outbreaks involving person-to-person, animal contact, environmental contamination, and indeterminate modes of transmission (<http://www.cdc.gov/nors/about.html>). No other such regional or national case-based system exists in the United States for reporting of HAB-related human illness, HAB-related animal illnesses, or HAB events.

OHHABS enables state and territorial health departments to electronically report, maintain, and have direct access to their records for HAB events and HAB-related human and animal cases. State and territorial health departments have the ability to create an OHHABS report starting with any HAB-related event or illness where information is available (e.g., if a state only has

information about a HAB-related human illness, the state may create a report for the HAB-related human case). Minimal data elements will be required (e.g., date of illness onset, state of exposure) for a report to be created in OHHABS.

Access to OHHABS will be limited to OHHABS account holders. Similar to NORS, user access for OHHABS at the state and territorial levels will be available at different levels of access, including read-only, read-write, and administrative user accounts within their states/territories. CDC administrators will be granted access to all user accounts and records for management purposes. CDC will provide user support and training, including guidance documents that will be available electronically.

4. Efforts to Identify Duplication and Use of Similar Information

Although other federal agencies (e.g., Environmental Protection Agency, Food and Drug Administration, United States Geological Survey) have interest in HABs, no system exists to collect HAB event information and HAB-related case information for humans and animals.

CDC staff along with the HAB Working Group (16 voluntary state partners and 7 federal partners) did not identify a similar regional or national surveillance effort in operation in the United States. Additionally, CDC is coordinating with other federal agencies to ensure that there is no duplication of data collection and plans to optimize data use through future data linkages with other federal environmental data systems. Future data linkages may allow other federal agencies to identify HAB events reported in OHHABS to link it to their existing systems. For example if the United States Geology Survey collected toxin levels in their routine water monitoring database, they could identify a HAB event or HAB-related illnesses reported in OHHABS. -

5. Impact on Small Businesses and Other Small Entities

This collection of information does not involve small businesses or other small entities.

6. Consequences of Collecting Information Less Frequently

OHHABS data will be collected electronically throughout the year; if data were collected less frequently, there may be missed opportunities for response and prevention efforts. Ongoing surveillance of HAB-related illnesses is expected to aid in the timely detection of events and illnesses and improve data quality. These data will also be used to identify potential trends across geographical boundaries, to assess morbidity and mortality, and to improve existing human and animal case definitions.

7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

- A. A 60-day Federal Register Notice was published in the *Federal Register* on 07/21/2015, Vol 80, No. 139, pp. 43090-43091. No comments were received.
- B. Consultation outside the Agency with Federal partners has included the Agency for Toxic Substances and Disease Registry (ATSDR), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the National Oceanic and Atmospheric Administration (NOAA), the United States Geological Service (USGS), the National Park Service (NPS), and the International Joint Commission (IJC). With state public health departments, consultation has included Florida, Illinois, Indiana, Iowa, Kansas, Maryland, Massachusetts, Michigan, Minnesota, New York, Ohio, Oregon, South Carolina, Virginia, Washington, and Wisconsin.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

[OHHABS will collect data on HAB environmental events and HAB-related illnesses including single human case reports and, single animal case reports from state and territorial health departments that conduct HAB surveillance.](#) Personally identifiable information will not be collected; state and territorial health departments may collect personally identifiable information to support local or state public health activities but this information is not stored or collected in [OHHABS](#).

Access to [OHHABS](#) will be limited to users with an account and may be further restricted by user account type. Individual states and territories will have access to [OHHABS](#) data in accordance with established data-use guidelines and the electronic user account permissions; CDC staff will have access to data according to user account permissions. [OHHABS](#) users will be required to agree to terms of use, also referred to as ‘Rules of Behavior.’

States and territories may create and manage records and enter [OHHABS](#) data including information such as age (in years), gender, and state of exposure, county of exposure (but not county of residence), case health history, and types of clinical testing performed. Exposure activities, exposure settings, algal bloom descriptions, and signs and symptoms of illness will also be collected. These data have no personal identifiers and cannot be used to distinguish individuals.

State participation in the surveillance collection is voluntary. Personally identifiable information is not submitted to CDC; however, state and local health departments might collect and store personally identifiable information locally to support local disease control activities related to HABs.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

A CDC human subjects advisor has determined that these activities are considered routine surveillance activities. Consistent with current CDC policy, routine surveillance activities do not meet the regulatory definition of research, and are therefore outside the scope of IRB review requirements. (Attachment D)

Questions regarding highly sensitive information including social security numbers and photographic identifiers will not be asked. Epidemiologic characteristics such as age, sex, and geographic location are routinely collected because of their significance in resolving public health problems. These questions will be asked in a general format, e.g., age (in years) rather than date of birth is collected. Clinical laboratory data and health illness information (signs and symptoms) are essential to proper identification and control of HAB-related illnesses and will be collected without laboratory or clinical identifiers for human cases of illness.

12. Estimates of Annualized Burden Hours and Costs

A. The total burden estimate for the collection of data elements is shown in Table 1. State Epidemiologists will complete the forms. There are 57 of them and we estimate they will need to complete the forms approximately 3 times per year. Burden estimates are based on previous experience with these instruments. The total burden estimate is 57 hours. (Table1)

Table 1 – Estimate of Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
State Epidemiologists	One Health Harmful Algal Bloom System (OHHABS) (electronic, year-round)	57	3	20/60	57
Total					

B. Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations - medical and health services managers in state government (<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>). Based on DOL data, an average hourly wage of \$42 is estimated.

Table 2 – Estimate of Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
State Epidemiologist	One Health Harmful Algal Bloom System (OHHABS) (electronic, year-round)	57	\$42	\$2394

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no capital and maintenance costs incurred by respondents.

14. Annualized Cost to the Government

Table 14-1: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Total Costs to the Federal Government	Personnel- Software development, support, and management	\$90,578

15. Explanation for Program Changes or Adjustments

This is new data collection. Similar data collection efforts were conducted as HABISS (0920-0004) from 2009 to 2011, but collection efforts in HABISS were discontinued due to defunding.

16. Plan for Tabulation and Publication and Project Time Schedule

Data collected through [OHHABS](#) will be compiled and analyzed on an annual or biennial basis. Summary reports will be distributed within the public health community and to state and federal partners.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

[OHHABS](#) is considered ongoing routine surveillance through an electronic system and will perform continuous collection of data. The OMB control number for [OHHABS](#) will be clearly posted on all information collection materials along with the approved expiration date and burden statement.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

List of Attachments

Attachment A, Section 301 of the Public Health Service Act (42 USC 241)

Attachment B, 60 Day Federal Register Notice

Attachment C, [One Health Harmful Algal Bloom \(OHHABS\)](#) data elements (electronic, year-round)

Attachment D, IRB determination

[Attachment E, OHHABS Case and Event Definitions](#)

[Attachment F, OHHABS Reporting Workflow](#)