

One Health Harmful Algal Bloom System (OHHABS)

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Request for OMB approval of a Revision to an approved Information
Collection

Supporting Statement A

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The Centers for Disease Control and Prevention (CDC), National Center for Emerging and

- 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 to support the

Zoonotic Infectious Diseases requests a three-year extension for the One Health Harmful Algal Bloom System (OHHABS) for harmful algal bloom (HAB) and HAB-associated illness surveillance.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases requests a three-year extension for the One Health Harmful Algal Bloom System (OHHABS) for harmful algal bloom (HAB) and HAB-associated illness surveillance.

Harmful algal blooms (HABs) are the rapid growth of algae or cyanobacteria (also called blue-green algae) that can cause harm to people, animals, or the local ecology. 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 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-associated illnesses and events.

HABs are an emerging public health concern. For 2016—2019, 22 states adopted use of the One Health Harmful Algal Bloom System (OHHABS) and entered 669 reports, including information about 452 human illnesses and at least 481 animal illnesses associated with HAB events. HAB events in fresh water, the result of cyanobacterial blooms, have been frequently reported in OHHABS. Of the 669 HAB event reports, 84% were associated with freshwater, resulting in 428 (95%) of human illnesses. In these freshwater settings, the most common signs and symptoms reported include gastrointestinal, generalized (e.g., headache, fever, fatigue), and dermatologic.

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-associated foodborne exposures were identified for 273 case reports of human illness through a separate 5-year data collection effort with a subset of states. Of these reports, 248 reported ciguatera fish poisoning or poisoning by other toxins in seafood, including saxitoxin and brevetoxin (Backer et al, 2015). A review of national outbreak data reported to CDC for the time period 1998-2015 identified outbreaks of ciguatera fish poisoning (CFP) as the second most common cause of fish-associated foodborne disease outbreaks in the United States, among those outbreaks with a confirmed etiology. For this time period, 227 CFP outbreaks resulted in 894 illnesses and 96 hospitalizations (Barrett et al, 2017). For 2016-2018, an additional 47 outbreak investigations implicated ciguatoxins, resulting in 147 illnesses and 12 hospitalizations (CDC, NORS Dashboard, January 21, 2022).

Domestic animal, livestock, and wildlife HAB-associated illnesses have also been documented in the United States. Between 2016 and 2019, 79 cases of domestic pet illness were reported to OHHABS, with 39% (n=31) resulting in death. During the same time period, there were at least 53 livestock illnesses and 349 wildlife illnesses reported. The majority of livestock (96%) and

wildlife (58%) died.

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) or economy (e.g., beach closures, shellfish bed closures). There is evidence that the frequency and severity of HABs may be affected by climate change, but that the impacts might vary due to the causal species, bloom location, or other factors. (Smucker et al, 2021; Anderson et al, 2021).

In response to HAB-related public health events in 2018, Congress appropriated funds to CDC to enhance harmful algal bloom exposure activities, including surveillance, mitigation, and event response efforts. In years since, Congress has directed CDC to continue efforts to respond to HAB events, including OHHABS as a tool for national surveillance. OHHABS is a centralized data source for public health surveillance of HAB events and HAB-associated illnesses. It uses a One Health approach that takes into consideration information from the environment, animal cases, and human cases. Outbreaks of HAB-associated 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. OHHABS is the national database used for public health surveillance of HAB events and single cases of HAB-associated human or animal illness. A standardized data-collection system for HAB events and HAB-associated illnesses continues to be necessary to quantify and characterize HAB-associated illnesses, refine HAB event and case definitions, and inform One Health prevention efforts.

OHHABS was approved for data collection in 2016. The system was launched in June 2016 along with a CDC HAB-associated illnesses website to provide more information for the general public about potential illnesses and to share resources for HAB awareness and OHHABS with public health partners. Since 2016, CDC has provided technical assistance and training to states and territories interested in OHHABS and worked with contractors to implement new features for OHHABS. In 2020, CDC and partners published the first summary of OHHABS data (years 2016—2018) in the Morbidity and Mortality Weekly Report (MMWR). (Roberts et al, 2020). In 2021, CDC released a 2019 OHHABS data summary online (<https://www.cdc.gov/habs/data/index.html>) and upgraded the electronic platform to improve the user interface and system functionality. During this time CDC has also continued to coordinate a series of conference calls where state and federal partners may discuss their surveillance activities, needs, and priorities. CDC has also had the opportunity to communicate with additional HAB surveillance stakeholders, such as members of the veterinary community, state and federal environmental health staff, and others to provide information about OHHABS reporting through webinars, posters, and other presentations.

This activity is authorized by Section 301 of the Public Health Service Act (42 USC 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/territorial level to identify and characterize HAB events, HAB-associated illnesses, and

HAB exposures in the United States and 2) to better inform and improve our understanding of HAB-associated illnesses and exposures through routine surveillance to inform public health policy and illness prevention efforts. OHHABS (electronic, year-round collection) includes questions about HAB events and HAB-associated-illness for human and animal cases. OHHABS, a web-based reporting system, is nationally available for state and territorial health departments to voluntarily report information about HAB-associated human and animal cases and HAB events.

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

As with all routine public health surveillance conducted by CDC, participation by states and territorial health departments with OHHABS is voluntary. Participating states and territories will remain 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-associated human and animal case definitions, which were created for OHHABS with input from state and federal partners, are available online to assist states and territories (<https://www.cdc.gov/habs/pdf/ohhabs-case-and-event-definitions-table-508.pdf>). States and territories that lack state-specific case and event definitions may use the HAB-associated human and animal case and HAB event definitions to identify suspect, probable, and confirmed HAB-associated cases and HAB events, respectively, to report to OHHABS.

CDC will use the information provided by states and territories in OHHABS to identify and address knowledge gaps related to HAB exposures and illness. For example, knowledge gained from surveillance practice and resulting data may inform the refinement of HAB event and HAB-associated human and animal case definitions. OHHABS data are also used to help characterize temporal and spatial trends of HAB-associated illnesses and health risks from HAB events, which can inform public health prevention and response in the United States. CDC recognizes the additional utility and need for OHHABS data dissemination. CDC has a data request process for OHHABS data and a routine process for releasing OHHABS data in summary reports.

3. Use of Improved Information Technology and Burden Reduction

OHHABS is a web-based, password-protected reporting system which supports reporting to CDC from state and territorial public health departments. OHHABS is unique; no other such regional or national case-based system exists in the United States for reporting of HAB-associated human illness, HAB-associated 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-associated human and animal cases. State and territorial health departments have the ability to create an OHHABS report starting with any HAB event but skip ahead to report an associated illness where information is available (e.g., if a state only has information about a HAB-associated human illness, the state may create

a report for the HAB-associated human case). Minimal data elements are required (e.g., date of illness onset, state of exposure) for a report to be created in OHHABS.

Access to OHHABS will continue to 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 continue to 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 public health surveillance system exists to collect HAB event information and HAB-associated case information for humans and animals.

CDC staff engaged with a group of state and federal partners (16 voluntary state partners and 7 federal partners) during the development of OHHABS. They 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 or illnesses reported in OHHABS to link to their existing systems. For example, if the United States Geological Survey collected toxin levels in their routine water monitoring database, OHHABS could be queried for a reported HAB event or HAB-associated illnesses in that water body. Similarly, data from a water monitoring database could potentially be used to provide supporting evidence of a HAB event in a water body as part of HAB event and illness reporting.

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-associated 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 November 16, 2021, Vol. 86, No. 218 pp. 63395-63396 (attachment B). No public comments were received.
- B. Prior to OMB approval in 2016, consultation outside the Agency with Federal partners 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 included Florida, Illinois, Indiana, Iowa, Kansas, Maryland, Massachusetts, Michigan, Minnesota, New York, Ohio, Oregon, South Carolina, Virginia, Washington, and Wisconsin.

CDC continues to regularly engage with state and federal partners on HAB surveillance.

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 continue to collect data on HAB events and HAB-associated 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 ‘Terms of Use.’

States and territories may create and manage records and enter OHHABS data including information such as age (in years), gender, 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.

A Privacy Impact Assessment is included with this submission (Attachment G).

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-associated illnesses and will be collected without laboratory or clinical identifiers for human cases of illness.

12. Estimates of Annualized Burden Hours and Costs

A. A total of 57 reporting sites are available in OHHABS (50 states and 7 United States territories). As of January 2022, 26 states have adopted OHHABS. Additionally, the number of states submitting reports may vary each year. For the purposes of calculating the estimated annualized burden, the total number of reporting sites available to report (n=57) is used as the number of respondents.

For the 2019 reporting year, OHHABS received 242 reports. This equates to an average of 4.25 reports per reporting site (242/57). This was rounded to 4 for burden calculation purposes. It is estimated that filling out a report form will take approximately 20 minutes, although this might vary based on the number of cases associated with an event. Based on these figures, the total estimated annualized burden is 76 hours (57 respondents*4 responses*.33 hours).(Table 1).

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/Territory	One Health Harmful Algal Bloom System (OHHABS) (electronic, year-round)	57	4	20/60	80/60
Total					76

B. Estimates for the average hourly wage for respondents are based on the Bureau of Labor Statistics mean hourly wage for epidemiologists. The hourly wage rate is \$40.20. This has increased from \$33.49 during the original OMB submission for OHHABS. See https://www.bls.gov/oes/current/oes_nat.htm#00-0000. The total estimated annual cost burden is \$3,055.20.

Table 2 – Estimate of Annualized Burden Costs

Type of	Form Name	Total Burden	Hourly Wage	Total
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Respondent		Hours	Rate	Respondent Cost
State/Territory	One Health Harmful Algal Bloom System (OHHABS) (electronic, year-round)	76	\$40.20	\$3,055.20
Total				\$3,055.20

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	\$92,500

15. Explanation for Program Changes or Adjustments

This is a revision request for an existing approval. The estimated annualized burden has increased from 57 to 76 hours, reflecting more recent data about the average number of reports submitted per reporting site, and accounting for additional states and United States territories that have the option to start reporting in OHHABS in the future.

An improvement is being made to standardize data collection, streamline data entry, and simplify data analysis. Responses to the existing 'EnSampleTested' field are now mapped to the original field, as well as an indicator variable ('EnTestingPerformed'). 'EnTestingPerformed' is set to 'Yes' if any type of sample (e.g., air, algae, finished water) was tested. Similarly, 'No Testing' and 'Unknown' in 'EnSampleTested' correspond to 'No' and 'Unknown' in 'EnTestingPerformed'. With this change, skip patterns can be used during data entry and the resulting data can be downloaded as two fields—one to indicate whether testing was conducted ('EnTestingPerformed') and one to describe the sample types tested 'EnSampleTested'.

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. CDC has released a MMWR report summarizing 2016-2018 data (Roberts et al, 2020) as well as an annual summary for 2019 data available online ([Summary Report – One Health Harmful Algal Bloom System \(OHHABS\), United States, 2019 | CDC](#)). Annual data for 2020 and 2021 are in the process of being finalized and summarized. .

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. Published 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

Attachment G. Privacy Impact Assessment

Attachment H. List of OHHABS reporting sites