

One Health Harmful Algal Bloom System (OHHABS)

OMB Control No. 0920-1105

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Request for OMB approval of an Extension Information Collection

Supporting Statement A

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- 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 understanding and prevention of HABs and HAB-associated illnesses.
- Data collected in OHHABS are accessible to state health departments, and will be available to federal partners and other stakeholders in the future to better characterize HAB events and single human and animal illness related to HAB exposures and to inform future prevention efforts.
- Data are 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 are voluntarily reported by state and territorial public health agencies.
- The data collected will be analyzed and presented through summaries and reports.

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.

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-associated illnesses and events.

HABs are an emerging public health concern. Several recreational water outbreaks associated with exposures to HABs in freshwater settings have occurred in the United States. For 2009-2014, 12 such outbreaks were reported to the CDC Waterborne Disease and Outbreak Surveillance System (WBDOSS). At least 69 persons experienced health effects such as dermatologic, gastrointestinal, respiratory, or neurologic symptoms. These reports represented 19% of the outbreaks associated with untreated recreational water for 2009-2014 and 80% of the HAB-associated outbreaks involving untreated recreational freshwater exposures that were reported to WBDOSS between 1978 and 2014. Additionally, the first reported outbreak to implicate contamination of a drinking water system occurred in September 2013. 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. At least 110 illnesses were reported to CDC as being associated with the outbreak.

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. A review of national outbreak data reported to CDC for the time period 1998-2015 identified outbreaks of ciguatera fish poisoning as the second most common cause of fish-associated foodborne disease outbreaks in the United States (Barrett et al, 2017).

Domestic animal and wildlife HAB-associated 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 is a centralized data source for public health surveillance of HAB events and HAB-associated illnesses using 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. However, there is currently no national database for HAB events or 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 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 both 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 HABs, with a focus on the Great Lakes region as part of CDC's Great Lakes Restoration Initiative activities. CDC has worked with contractors to develop new features for OHHABS. For example, the HAB-associated human and animal case and HAB event definitions have been incorporated into the electronic system so that these data fields may 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 also integrated a data review feature into OHHABS that allows administrative users to run and export a series of data completeness checks on their reports before marking them as final. CDC has also added features to support multijurisdictional data sharing as well as user-uploadable PDF forms. During this time CDC has also continued to engage routinely in a series of conference calls coordinated by CDC to talk with state and federal partners who conduct HAB surveillance about 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 and national 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. 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 recognizes the utility and need for OHHABS data dissemination. 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-associated human and animal illnesses. OHHABS data will also help characterize temporal and spatial trends of HAB-associated illnesses and health risks from HAB events, and will improve public health prevention and response in the United States. Looking forward, CDC plans to develop data processes to more fully and routinely assess the quality of, tabulate, analyze, and publish OHHABS data in surveillance summaries. 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-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 or 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 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 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 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 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-associated 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-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 October 15, 2018, Vol. 83, No. 199, pp. 51958-51960 (attachment B). Four non-substantive public comments were received (attachments B1-B4). Standard responses were sent.
- 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 environmental 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 '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. The OHHABS application is part of the NORS system. The NORS 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. The total burden estimate for the collection of data elements is shown in Table 1. State/Territorial epidemiologists or their designees will complete the form (attachment C). There are 57 reporting jurisdictions in OHHABS, so we estimate this to be the number of respondents and that 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, unchanged from the approved ICR (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/Territorial Epidemiologists	One Health Harmful Algal Bloom System (OHHABS) (electronic, year-round)	57	3	20/60	57
Total					57

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 \$33.49. See https://www.bls.gov/oes/current/oes_nat.htm#00-0000. The total estimated annual cost burden is \$1,908.93. This represents a decrease in burden of \$485.07. The decrease is attributable to

revised estimates of hourly wage rates.

Table 2 – Estimate of Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
State/Territorial Epidemiologist	One Health Harmful Algal Bloom System (OHHABS) (electronic, year-round)	57	\$33.49	\$1,908.93
Total				\$1,908.93

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 Explanation	Annual Costs (dollars)
Research Fellow	\$70,000
IT	\$55,000
Other staff	\$20,000
Total	\$145,000

15. Explanation for Program Changes or Adjustments

No changes or adjustments to the data instrument are being submitted with this extension.

Opportunities to more closely link OHHABS data collection with NORS may be examined using the current data collection instrument in order to simplify reporting HAB-associated outbreak data at case and outbreak units of analysis. CDC anticipates reviewing and publishing data from OHHABS.

Future data instrument changes may occur based on the results of a review. For supporting materials, CDC engages routinely in a series of conference calls coordinated by CDC to talk with state and federal partners who conduct HAB surveillance about their surveillance activities, needs, and priorities. This group is providing feedback on the case definitions that may lead to changes to this supporting documentation in the next 1-2 years. .

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. At the time of this request, CDC has not compiled and analyzed the data. CDC plans to develop processes for OHHABS so that data reported from 2016-2018 can be summarized and published. The system launched in June 2016, with 2016-2018 being initial years of adoption for multiple states. During this time CDC focused on system support, including new features. For example, CDC introduced an OHHABS system feature that enables system users to check data completeness when finalizing a report. Since HAB-associated illnesses and HAB events primarily occur in warm weather months, CDC would review 2018 as a calendar year after those months have passed.

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

Attachments B1 – B4. Public comment

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