

One Health Harmful Algal Bloom System (OHHABS)

OMB Control No. 0920-1105

Expiration Date: November 30, 2025

Request for OMB approval of a Revision

Supporting Statement A

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

Goal of the project: 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.

Intended use of the resulting data: Data collected in OHHABS are accessible to state health departments and made available to federal partners and other stakeholders to increase the use of the data for understanding HAB events and preventing associated illnesses.

Methods to be used to collect: Data are collected electronically, with data accessible via System for Enteric Disease Response, Investigation, and Coordination (SEDRIC), a secure CDC enterprise surveillance platform, that seamlessly integrates epidemiologic with laboratory data in real-time.

The subpopulation to be studied: Human and animal illnesses related to HAB exposures and environmental data about HABs are voluntarily reported by state and territorial public health agencies.

How the data will be analyzed: Collected data will be analyzed within SEDRIC and by analysts using statistical software like SAS and R, and presented through summaries and reports.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This is a revision Information Collection Request for the One Health Harmful Algal Bloom System (OHHABS) (OMB Control No. 0920-1105, expiration date 11/30/2025). We are requesting extended approval for a period of 36 months.

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 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 and growing public health concern. 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).

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 (Attachments F-H). 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 reporting 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). Since then, CDC has released OHHABS data summaries for the years 2019, 2020, 2021, and 2022 online (<https://www.cdc.gov/ohhabs/data/index.html>). 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.

In August 2024, OHHABS began a yearlong process of modernizing the OHHABS system and migrating data entry from the current stand-alone system into CDC's System for Enteric Disease Response, Investigation, and Coordination (SEDRIC) System; OHHABS will be fully integrated into SEDRIC in August 2025. As part of that process, CDC reviewed historical data and its current surveillance needs to determine how best to streamline questions and response options in each form (environment, human illness, animal illness), thus improving the quality of information submitted to OHHABS. Seven state partners representing 3 states who submit information to OHHABS reviewed and provided feedback to CDC in a series of meetings between September 12, 2024 and September 16, 2024.

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.

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/ohhabs/media/pdfs/ohhabs-case-and-event-definitions-table-508_1.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.

3. Use of Improved Information Technology and Burden Reduction

OHHABS is unique; no other such regional or national system exists in the United States for reporting of HAB-associated human illnesses, HAB-associated animal illnesses, or HAB events. After August 2025 OHHABS will reside in The System for Enteric Disease Response, Investigation, and Coordination (SEDRIC), which is DFWED's module in Data Collection and Integration for Public Health Event Response (DCIPHER), a secure, cloud-based CDC enterprise surveillance platform, that seamlessly integrates epidemiologic with laboratory data in real-time. The use of electronic data collection and secure integration limits the burden of needing to enter data from paper forms into an electronic format. There will be an effective difference in the time it takes the interviewer to fill in the OHHABS forms as electronic data due to the improved user interface system and streamlined forms to reduce burden of entry on partners.

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 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 coordinates 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.

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. No special circumstances apply.

The use of the less detailed options for the collection of race and ethnicity data is because the potential benefit of collecting detailed race and ethnicity data does not justify the additional burden to state/territory partners to collect detailed data along with the risk of respondents' privacy or confidentiality given the somewhat specific nature of HAB events.

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 8, 2024, Vol. 89, No. 217 pp. 88776-88777 (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. In 2024, feedback on the new forms was gathered from public health professionals who work in HABs in California, Utah, and Michigan.

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

Individuals and organizations will be assured of the privacy of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose without their prior consent, unless required by law upon the demand of a court or other governmental authority.

These data elements and collection tools will ascertain information from respondents about exposures (food and other) preceding an onset of illness. It will not collect any information that could be used to identify individual patients. Local or State public health officials with jurisdictional responsibility will maintain the respondent's name, telephone number, and other personally identifiable information. This information will not be included in the data collection tool and no identifying information will be transmitted to CDC.

State participation in the surveillance collection is voluntary. Data will be kept private to the extent allowed by law.

This information collection request has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases and it has been determined that the Privacy Act does not apply to this information collection request. No Personally Identifiable Information (PII) or Personal Health Information (PHI) is being collected. This collection, however, is being completed through System for Enteric Disease Response, Investigation, and Coordination (SEDRIC), a part of Data Collation and Integration for Public Health Event Responses Software as a Service (DCIPHER SaaS). There are no changes to Privacy aspects of this package. The latest approved Privacy Impact Assessment (PIA) for Data Collation and Integration for Public Health Event Responses Software as a Service (DCIPHER SaaS) is attached).

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). 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.

The use of the less detailed options for the collection of race and ethnicity data is because the potential benefit of collecting detailed race and ethnicity data does not justify the additional burden to state/territory partners to collect detailed data along with the risk of respondents' privacy or confidentiality given the somewhat specific nature of HAB events.

12. Estimates of Annualized Burden Hours and Costs

We estimated annualized burden hours based on historical data of the actual number of respondents to OHHABS between 2018 and 2022. Specifically, we estimated 300 annual environmental reports, 90 human reports, and 130 animal reports, by taking the average number of reports submitted to OHHABS during 2018–2022. We had 6 CDC employees use mock scenarios to pilot test the updated forms and then document time to complete the form in order to calculate burden time averages: the environmental form averaged 10 minutes, the human form 8 minutes, and the animal form 5 minutes. Actual response times may vary based on the number of cases associated with an event. Based on these figures, the total estimated annualized burden is 73 hours (Table 1).

Table 1 – Estimate of 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
State/Territory	One Health Harmful Algal Bloom System (OHHABS) Environmental Form (Att F)	300	1	10/60	50 hours
State/Territory	One Health Harmful Algal Bloom System (OHHABS) Human Form (Att G)	90	1	8/60	12 hours
State/Territory	One Health Harmful Algal Bloom System (OHHABS) Animal Form (Att H)	130	1	5/60	11 hours
Total					73 hours

B. Estimates for the average hourly wage for respondents are based on the 2023 Bureau of Labor Statistics mean hourly wage for epidemiologists. The median hourly wage rate is \$43.48 This has. See https://www.bls.gov/oes/current/oes_nat.htm#00-0000.

Table 2 – Estimate of Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
State/Territory	One Health	73	\$43.48	\$3,174.04

	Harmful Algal Bloom System (OHHABS) (electronic, year-round) (Att F, G, H)			
Total				\$3,174.04

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

There are no capital and maintenance costs incurred by respondents other than their time to participate.

14. Annualized Cost to the Government

Hourly wage for federal government employees are based on Office of Personal Management (OPM) FY2024 government service (GS) rates for Atlanta, GA. See https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/ATL_h.pdf. The estimated total cost to the Federal Government for this project is \$14,994.00 over a one-year period of data collection. Therefore, a three-year collection period is estimated to cost \$44,982.00. Exhibit 14.1 provides a breakdown of the estimated total annual costs.

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

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
Epidemiologist – (GS-12); Epi project development and project management, data management, data analysis, publication, and dissemination of results	200	\$44.03	\$8,806.00
Epidemiologist -- (GS-14) System oversight, data analysis, data dissemination	100	\$61.88	\$6,188.00
Estimated Total Cost of Information Collection			\$14,994.00

15. Explanation for Program Changes or Adjustments

Changes of overall annual burden from the previous submission is due to the separation of the data collection instruments. The data collection instruments (environmental form, human form, and animal form) were separated out because not all three forms are required for submission to OHHABS. With the separation of these data collection instruments, a more accurate estimation of overall annual burden hours was calculated using averages from a 5-year data collection time, and a mock pilot test of the revised forms resulting in 73 overall hours of burden. Previously number of respondents was 57 based on number of potential reporting sites, number of responses per respondent was 4 calculated by the average number of forms submitted by reporting sites, the average burden of response was estimated at 20 minutes resulting in 76 overall hours of burden.

While the forms have been separated out as part of this revision these are not new forms to OHHABS.

Updates to OHHABS were made to better align with HAB information as we know it today. Changes include: removing questions that no longer need to be assessed, adding new questions to assess emerging needs, streamlining data collection methods, re-wording of existing questions to better align with Agency standards and other OMB-approved questionnaires. A detailed list of changes can be seen in the “OHHABS Summary of Changes” document (Attachment E).

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](#)). Annual summary reports have been made available online for [2019](#), [2020](#), [2021](#) and [2022](#).

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

OHHABS is considered ongoing routine surveillance through an electronic system and will perform a 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. Authorizing Legislation
- Attachment B. 60 Day Federal Register Notice
- Attachment D. Human Subjects Determination
- Attachment E. Summary of Changes
- Attachment F. Environmental Form
- Attachment G. Human Form
- Attachment H. Animal Form