

**SUPPORTING STATEMENT
COMPREHENSIVE AQUACULTURE HEALTH PROGRAM –
USE OF MI-CO APPLICATION
OMB Control No. 0579-XXXX**

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

This is a new information collection request.

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) unit is responsible for protecting the health of the nation’s aquatic livestock and supporting safe trade of those animals and their products. This authority is provided under the Animal Health Protection Act, 7 U.S.C 8301 *et seq.* VS has further authority under Executive Order 13921, Promoting American Seafood Competitiveness and Economic Growth, which rescinded the 2008 National Aquatic Animal Health Plan and authorized a new national aquaculture health plan establishing USDA as the competent authority for the protection, inspection, and certification of aquatic livestock health.

The new national plan, [National Aquaculture Health Plan and Standards](#) (NAHPS), provides guidance for pathogen testing, reporting, and laboratory standards in addition to outlining health inspection options for aquatic livestock. One of these inspection options is the Comprehensive Aquaculture Health Program Standards (CAHPS). CAHPS was developed in partnership with the U.S. aquaculture industry as a voluntary program which establishes a framework to improve and verify the health of aquatic livestock produced in the United States. Principles outlined in the CAHPS provide for early disease detection, surveillance, risk mitigation, reporting, and response for the control of aquatic animal pathogens—especially those reportable to the World Organization for Animal Health (WOAH)—and to prevent their dissemination via aquatic animal sale, movement, and trade.

VS and the aquaculture industry are implementing the CAHPS pillars via program standards. These standards follow international (e.g., WOAH) guidance on demonstrating animal health to meet the demand from international markets and trading partners to oversee and improve aquatic animal health disease detection, reporting, and health verification in the United States. Voluntary adoption of CAHPS will protect aquatic livestock from disease, afford early disease detection, expand aquaculture business opportunities, and improve resource protection and environmental sustainability.

Aquaculture entities will participate as CAHPS Premises. This participation requires (1) implementing the five pillars of the program standards and the associated activities at the desired

level determined by the business goal of the participant, and (2) allowing USDA to inspect and verify compliance with the standards for the determined health targets.

VS is asking OMB to approve, for 3 years, its use of a MI-Corporation (MI-CO) application (or app) in connection with VS' efforts to implement the CAHP pillars and continually improve the health and marketability of the U.S. aquaculture populations and their products.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

CAHPS is designed to evaluate and verify aquatic livestock health on a premises. The premises may have a single aquatic livestock population or multiple populations with different certification needs. If animal groupings are epidemiologically linked (i.e., connected in ways that might allow pathogen exchange), these groupings are considered a single population with all health risks determined to be equivalent across the animal holdings on the premises and claim a universal health status under CAHPS. If animal populations are epidemiologically distinct (i.e., separated in ways that prevent pathogen exchange), these groupings are considered separate populations, each with its own classification and health status (independently sampled, tested, and assessed) under CAHPS. Therefore, the number of pathogens of concern and the number of populations on a premises will determine the amount of information collected for each population and the desired associated health claims to support animal health verification. The level and type of health verification is driven by customers' business needs and/or State, country, or trading partner requirements.

Each premises identifies its own Aquatic Animal Health Team (AAHT). This team collects and analyzes data to demonstrate to VS that all pillars of CAHPS are implemented and premises are managing risk sufficiently to protect and maintain animal health claims demonstrated through pathogen testing. This information will be collected and housed at the premises and VS will conduct biannual audits. One audit will be conducted virtually for VS SMEs to review, with the premises' AAHT, the status of pathogen surveillance and early detection systems. VS personnel will conduct the second annual audit on the premises to review documentation, observe risk mitigation practices, and verify testing data meets the declared health target.

During the onsite inspection, VS personnel will use the MI-CO CAHPS app to verify compliance with program standards. The MI-CO app will retain information from inspection to inspection. VS will update participants' information annually. VS will not physically collect or remove from the premises any of the documentation described below unless the participant gives express permission to attach documents, such as a biosecurity plan, CAHPS workbook, surveillance plan, or disease investigation plan to their CAHPS portfolio in the app¹.

VS personnel will annually review and enter information for every CAHPS participant to support compliance with CAHPS, including the general information and information and documentation

¹ VS anticipates that, at least initially, these will be the only documents attached to stakeholder profiles in the app; other data will be verbally/visually collected.

for each pillar of the program standards. If no information or plans change, subsequent data collection may be abbreviated. VS anticipates that the first year of CAHPS participation will incur the lengthiest data collection impact.

General Participant Information² (Business)

This general information is needed for VS to have a clear understanding of the specific aquaculture business including premises description, where livestock are held, and the purpose of the business:

- Premises name and address (GPS if possible).
- Assigned VS registration number (e.g., export registration number or premises ID).
- Declaration of CAHPS participation.
- Premises type.
- Premises description.
 - Property location and boundaries.
 - Locations and types of structures on the property.
 - Locations, numbers, and types of aquaculture systems on the property.
 - Number and type of holdings in each system,
 - Direction of water, personnel, and (if applicable) vehicle flow throughout the premises.
 - Premises map.
 - Nearest facilities or water bodies with similarly susceptible aquatic animal populations.
- Farm gate commodity (e.g., live animal, processed product, dead animal).
- Intended end use of commodity (e.g., human consumption, further grow-out, broodstock, pets/display, bait, stock enhancement, feed ingredients).
- Destination of commodity (e.g., international, interstate, intrastate).
- Networked premises (e.g., other similarly owned or connected farms through animal movement, processing, ownership).
- Number and description of animal populations on premises, including:
 - Life-stages of each species.
 - Physical groupings (by structure and system) of each species/life-stage on the property.
 - Additional information that distinguishes groupings (e.g., year-class, parentage, or end-use).
 - Pathways for pathogen exchange, including:
 - Linkages between aquatic animal groupings on the premises.
 - Linkages with aquatic animal groupings on other premises (i.e., contact networks) if applicable.

Pillar 1: Aquatic Animal Health Team (Business)

This information assures VS that the premises has the expertise to oversee CAHPS implementation and compliance.

- Names, contact information and affiliation of members.

² VS is currently working with APHIS Regulatory Analysis and Development staff to draft regulations codifying and implementing CAHPS. Until then, all sections rest on the authority of the CAHPS program standards.

- Roles and responsibilities of members.
- Name and contact information for aquatic animal laboratory conducting testing.
- Documented plans:
 - Communication plan for health inspections and status updates.
 - Biosecurity plan for all pathways of concern for each pathogen of concern.
 - Official annual surveillance plan for all pathogens of concern.
 - Disease investigation and reporting plan.
 - Response and recovery plan.
 - CAHPS workbook (includes a managed introduction risk (MIR) worksheet for CAHPS Global³).
- Training program for premises employees on biosecurity and early pathogen detection.

Pillar 2: Risk Evaluation (Business)

This information provides transparency on the specific pathogens of concerns for the premises and identifies the pathways of pathogen introduction for the premises as well as the mitigation practices (e.g., biosecurity plan) implemented to eliminate or minimize pathogen introduction risks via each pathway.

- List of pathogens of concern, including WOAH-listed and other pathogens of concern and design health target (e.g., assumed pathogen prevalence level, so a surveillance plan can be designed) for each pathogen.
- Identification of risk pathway control points on farm for pathogens of concern. Typically, for most aquaculture operations, pathways include incoming animals, water sources, feed sources, vectors, and fomites.
- Risk mitigation (e.g., biosecurity plan) practices for each pathway of risk (including animal sources, water sources, feed sources, fomites, and vectors) for each pathogen of concern.
 - For CAHPS Global participants this also includes the premises' AAHT MIR evaluation and determination if the pathway is secured or managed (captured in the CAHPS workbook).

Pillar 3: Early Detection System (EDS) and Official Surveillance (Business)

CAHPS participants must implement practices to ensure early disease detection capabilities, including broad, non-specific testing methods as well as an annual surveillance plan that meets trade partner requirements and/or achieves design health status target (e.g., assumed pathogen prevalence level).

- Early detection system (EDS) strategies including records documenting monitoring for morbidity and mortality and changes to production metrics (e.g., animal behavior or production changes), and broad routine health screening practices.
- Official annual surveillance plan that meets target health status including sampling strategies for representative sampling of the population(s).
- Laboratory test reports/results.

³ CAHPS Global is the highest level of participation. CAHPS Global is structured to support the most rigorous demands of international trade partners, including premises freedom declarations at 95 percent confidence and 2 percent detection prevalence levels.

- Analysis of testing and test results to show design health target is achieved, including declaration by accredited veterinarian, when necessary, that declared health design target is met.

Pillar 4: Disease Investigation and Pathogen Reporting (Business)

This pillar is designed to ensure that when normal or acceptable levels of morbidity and mortality exceed background levels a plan is in place to address disease outbreaks. If the outbreak is suspected or is determined to be caused by a WOAHA listed pathogen or a State listed pathogen, the premises has a protocol to appropriately report the detection to State and/or Federal authorities.

- Determination of acceptable (e.g., background) morbidity and mortality rate thresholds.
- Disease investigation and reporting plan, including on-premises communication to avoid spread of an infectious agent.

Pillar 5: Response and Recovery (Business)

This pillar is designed to ensure that the premises has a plan for response to both infectious and non-infectious disease outbreaks. A strawman plan is acceptable and should include options for vaccine, treatment, depopulation and cleaning and disinfection.

The response plan should include:

- Cleaning and disinfection practices.
- Ability to isolate affected animals/populations.
- Strategies to respond to disease outbreak.

In addition to the information collected above using the MI-CO app, the VS inspector will review the following documents and attached to MI-CO profile for CAHPS participants. These documents are developed by the AAHT and include:

- **Communication Plan for the AAHT (Business):**
 - Details internal communication for the aquatic animal health team – frequency (e.g., weekly, monthly) and type of routine communication (e.g., email, reports) on animal health as well as provision for times of disease events.
 - Reviewing this document affords VS confidence that everyone on the AAHT is aware of the animals’ health status.
- **Biosecurity Plan for all pathways of concern for each pathogen of concern (Business):**
 - Details the results of premises risk evaluation for all pathogens of concern for each control point.
 - Describes practices and treatments implemented to eliminate or reduce the risk of pathogen introduction and spread.
 - Should include cleaning and disinfection practices and following.
 - Review of this document and corresponding premises site visit ensures that procedures are in place to avoid risk of pathogen introduction and affords confidence in the stability of health testing results.

- **Official annual Surveillance Plan for all pathogens of concern (Business):**
 - Details sampling and surveillance practices including frequency of sample collection, chain of custody, sampling shipping practices, and how data will be analyzed.
 - Review allows VS to verify the facility has appropriate procedures to recognize animal or premises health status.
- **Disease investigation and reporting plan (Business):**
 - Details morbidity and mortality thresholds for the premises and outlines steps for a disease investigation when those thresholds are exceeded.
 - Review allows VS to verify participant has a plan for disease incursions and response. VS understand that this plan may be vague and limited as may vary depending on disease situation.
- **Response and recovery plan (Business):**
 - Details premises-specific approach to respond and recovery from disease incursions. Plan may include vaccination options as well as procedures for treatments and depopulation.
 - Review allows VS to verify participant has a plan for disease incursions and response.
- **CAHPS workbook (includes MIR for CAHPS Global) (Business):**
 - VS supplies this workbook to assist participants in addressing each CAHPS pillar and determining if pathways are secured or mitigated for CAHPS Global participants.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

APHIS makes every effort to comply with the E-Government Act, 2002 (E-Gov) and to provide for alternative submission of information collections.

VS personnel conducting CAHPS on-farm compliance inspections will use a MI-CO platform for a server/client-based mobile application that supports data collection using forms that can be deployed to a mobile device, like a smartphone or tablet, and used in an internet-connected or disconnected environment. Additionally, forms can be accessed via a web browser on an internet-connected device. All data collection, regardless of method, is stored on the MI-CO server for further processing and delivery to official VS systems such as Surveillance Collaboration Services (SCS) or the VS Analytics Warehouse.

The MI-CO app has been granted an Authority to Operate (ATO) by USDA under the SCS accreditation boundary. It has met the requirements of National Institutes of Standards and Technology (NIST) 800-53 ([SP 800-53 Rev. 5, Security and Privacy Controls for Info Systems and Organizations/CSRC \(nist.gov\)](#)), USDA, and the Federal Information Security Modernization Act. Given those classifications, the app meets and maintains all USDA and

Marketing and Regulatory Programs-Information and Technology Division cybersecurity standards for ensuring confidentiality, integrity, and availability of data.

Information collected using the app demonstrates compliance with CAHPS. The MI-CO app was designed using decision trees that formed the for the CAHPS pillars described in Question 2. Answers to questions posed in the app will confirm the implementation of CAHPS as well as provide the CAHPS participant with an annual report and farm map, if desired. Data entered in the app will remain there until it is updated at the next inspection.

Use of the MI-CO CAHPS app will streamline on-farm inspections as well as make the inspections more consistent across all CAHPS participants. On-farm inspectors will still have to review pathogen testing laboratory reports and biosecurity practices, but this will be for verification only.

APHIS anticipates 100% of the responses will be electronic.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

The information that VS collects is not available from any other source. VS is the only Federal agency responsible for verifying the health of farmed aquatic livestock.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The information VS collects is the minimum needed to verify the health status of aquatic livestock populations and assure that on-farm practices are adequate to prevent or minimize the risk of introducing identified pathogens of concern onto the farm. Approximately 80 percent of the respondents in this information collection are small entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

This is an ongoing information collection and participation in the program is voluntary. If the information were collected less frequently or not collected, VS could not effectively monitor the health of the nation's aquatic livestock populations.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

- **requiring respondents to report information to the agency more often than quarterly;**

- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

There are no special circumstances associated with this information collection. This information collection is conducted in a manner consistent with the guidelines established in [5 CFR 1320.5](#).

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

VS engaged in productive consultations with the following individuals concerning the information collection requirements associated with this program. They provided feedback to VS staff about the CAHPS pillars, plans, and papers that VS will use the MI-CO app to record and document and will be among the anticipated respondents once VS begins using the application. They do not anticipate any difficulties or undue burden in carrying out the described activities.

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On Tuesday, October 24, 2023, APHIS published in the Federal Register on pages 72989 and 72990 (88 FR 72989) a 60-day notice seeking public comment. No comments from the public were received.

9. Explain any decision to provide any payment or gift to respondents, other than re-enumeration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C.552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

See APHIS Form 71 for hour burden estimates. Burden estimates were developed from discussions with aquaculture producers and industry representatives.

• Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

VS estimates the total annualized cost to respondents for this collection to be \$22,067.72. This was computed by multiplying the hours of estimated response time (378 hours) by the estimated average hourly wage of Farmers, Ranchers, and Other Agricultural Managers (SOCC 11-9013, \$40.29) and then multiplying the result (\$15,229.62) by 1.449 to capture benefit costs.

The average hourly rate was derived from the U.S. Department of Labor, Bureau of Labor Statistics Report – Occupational Employment and Wages in the United States.

<http://www.bls.gov/news.release/pdf/ocwage.pdf>.

According to DOL BLS news release USDL-23-0488 released March 17, 2023, employee benefits account for 31 percent of employee costs, and wages account for the remaining 69 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.449.

13. Provide estimates of the total annual cost burden to respondents or record keepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

No annual cost burden is associated with capital and startup costs, operation and maintenance expenditures, and purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

See APHIS 79. The annual cost to the Federal government is estimated to be \$30,456.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

This is a new collection.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

VS has no plans to publish information it collects in connection with this program.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

This collection does not involve any VS forms.

18. Explain each exception to the certification statement, "Certification for Paperwork Reduction Act."

VS is able to certify compliance with all the provisions under the Act.

B. Collections of Information Employing Statistical Methods

No statistical methods are associated with the information collection activities used in this program.