

Budget Change Proposal - Cover Sheet

Fiscal Year: 2020-21

Business Unit: 8570

Department: Department of Food and Agriculture

Priority Number: [Click or tap here to enter text.](#)

Budget Request Name: 8570-009-BCP-2020-GB

Program: 6570-Agricultural Plant and Animal Health; Pest Prevention; Food Safety Services

Subprogram:

Budget Request Description: Laboratory Information Management System for Food Safety Protection, Animal Disease Prevention, and Emergency Response

Budget Request Summary: The California Department of Food and Agriculture requests \$494,000 General Fund in Fiscal Year 2020-21 and \$515,000 in 2021-22 for Phase 1 of replacement of the California Animal Health and Food Safety Laboratory Information Management System which is reaching the end of its life-cycle.

Requires Legislation: Yes No

Code Section(s) to be Added/Amended/Repealed:

Does this BCP contain information technology (IT) components? Yes No

If yes, departmental Chief Information Officer must sign.

Department CIO Name:

Department CIO Signature:

Signed On Date:

For IT requests, specify the project number, the most recent project approval document (FSR, SPR, S1BA, S2AA, S3SD, S4PRA), and the approval date.

Project Number:

Project Approval Document:

Approval Date:

If proposal affects another department, does other department concur with proposal?

Yes No

Attach comments of affected department, signed and dated by the department director or designee.

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Date: 7/9/19

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Date: 7/10/19

Department Director: Kevin Masuhara

Date: 1/8/20

Agency Secretary: Karen Ross

Date: 1/8/20

Department of Finance Use Only

Additional Reviews: Capital Outlay: ITCU: FSCU: OSAE:

Department of Technology:

PPBA: Sergio Aguilar

Date submitted to the Legislature: 1/10/20

A. Budget Request Summary

The California Department of Food and Agriculture (CDFA) requests \$494,000 General Fund in Fiscal Year 2020-21 and \$515,000 in 2021-22 for the Animal Health and Food Safety Services Division (AHFSS) to begin replacement of the Laboratory Information Management System (LIMS) at the California Animal Health and Food Safety (CAHFS) Laboratory which is reaching the end of its life-cycle. For Phase 1, funding will be allocated to perform project management, document CAHFS' existing application, perform an "as is business process documentation", document mid-level requirements, conduct market research, and identify solution alternatives.

B. Background/History

LIMS is a CAHFS' core laboratory software system used to manage sample testing performed by CDFA personnel during routine and emergency animal disease and food safety incidents and serves as the only regulatory veterinary information system for animal health and food safety services in California. LIMS is obsolete and suffers from severe operational and functional deficiencies. Its replacement is required to access timely, accurate, secure and up-to-date program information and laboratory reports which are necessary to effectively monitor, detect and respond to emergency food safety and animal health disease incidents and outbreaks.

AHFSS and CAHFS are partners in the prevention, detection, and response to animal health disease outbreaks. Assembly Bill 2772 (Chapter 1536, Statutes of 1982) requires the Secretary of CDFA to contract with the University of California (UC) Regents and the UC Davis School of Veterinary Medicine to establish and operate poultry and livestock disease diagnostic laboratories to conduct tests and examinations for, and diagnoses of, livestock and poultry diseases. This was done to ensure that California maintained an accurate and rapid diagnostic testing capability for foreign and emerging animal diseases. This agreement also ensured that the laboratory system was accountable to CDFA and California's livestock and poultry industries, and that the priorities within the laboratory system would not shift to other areas with different objectives, such as research funded by other government agencies and private entities.

CAHFS is comprised of a network of four veterinary diagnostic laboratories statewide. The main laboratory, located on the UC Davis campus, serves Northern California producers and provides centralized administrative and information technology (IT) support for the entire laboratory system. The Turlock and Tulare laboratories provide testing services to thousands of animal-producing farms throughout the San Joaquin Valley. The San Bernardino laboratory provides diagnostic services to Southern California, including surveillance for high-consequence diseases that enter from Mexico. In addition, all laboratories provide services to thousands of hobby and backyard animal owners, as this is the population most at risk for introduction of an emerging or foreign animal disease like the current virulent Newcastle Disease (vND). CAHFS serves as the backbone of the State of California's early warning system to protect the health of California's livestock and poultry, and safeguards public health, food safety and California's agricultural economy by providing rapid and reliable testing and diagnoses for animal diseases, including those that are transmissible to humans.

To accomplish this mission, CAHFS processes approximately 450,000 samples per year

amongst its four laboratory locations throughout the State. Cases, test results, client communication/information and billing data are tracked using CAHFS' LIMS. LIMS is a software-based application that provides sample logging and associated customer data; sample test assignment, scheduling and tracking; quality control and sample test results; client communication records; fee estimates; and case reporting functions.

LIMS was last replaced following the 2002 virulent Exotic Newcastle Disease outbreak, which demonstrated that the previous system was unable to accommodate the sample load needed in an outbreak situation. The system went live in 2007, and since this time, CAHFS IT staff have continued to make in-house system improvements, fix software "bugs," integrate new equipment into the workflows, and build user interfaces to maintain a workable LIMS, which is required for CAHFS daily operations. More than eighty percent of CAHFS employees use LIMS daily and the system is used to provide information management needed for CAHFS to meet its accreditation requirements.

The existing LIMS architecture is based on inefficient and outdated design principles that cannot provide adequate information management infrastructure to meet and respond to modern testing needs required for animal health emergency outbreaks and daily business and does not allow for effective information exchange between CAHFS and CDFA. The system is now approximately twelve years old and is reaching the end of its life expectancy.

C. State Level Considerations

This proposal is consistent with the primary mission of CDFA, which is to promote and protect a safe and health food supply and to enhance local and global agricultural trade, through efficient management, innovation and sound science, with a commitment to environmental stewardship. This proposal is also in agreement with CDFA's strategic plan to provide a comprehensive prevention, response and surveillance system of adverse events that protects the agricultural, natural, and water conveyance and resources; and to make use of best available science in the development of policies, statutes, and regulations.

D. Justification

CAHFS and CDFA work in partnership to safeguard California's \$11.2 billion livestock and livestock product industry, and to protect public health and the food supply. Rapid diagnosis, information management and data exchange are critical to safeguard the industry and public health. Without a robust, modern, functioning LIMS, the State is vulnerable to a high consequence event with potentially significant negative economic impacts.

Funding for this proposal supports an integrated laboratory system to protect California agriculture and the public from diseases and food contaminants that fall within CDFA's core areas of responsibility. In both urban and rural areas, the growth of backyard livestock and poultry populations is on a steep incline exposing the public and commercial operations to the risk of infectious diseases. California is the nation's leading dairy state (collecting \$6.5 billion in revenue in 2017) and represents one of the most vulnerable animal populations for introduction

and rapid spread of a foreign animal disease anywhere in the world. California products account for approximately 33 percent of total United States exports of dairy products. Unchecked spread of disease in California's dairy population would cripple trade of United States products.

CAHFS LIMS processes mission-critical information required by CDFA and the United States Department of Agriculture (USDA) for emergency response efforts, such as sample collection and testing. It is important for LIMS to gather test results, geographic locations, and other pertinent information, and then electronically share data with AHFSS' Emerging Threats Information Management system (ET) so test results can be linked with CDFA's emergency response activities. This information is critical to identify the affected facilities, establish effective quarantine zones, and determine appropriate sample protocols to contain disease outbreaks and determine when a disease has been eradicated. Failure to do so can result in devastating economic losses, as well as the destruction of potentially infected livestock and poultry. A 2011 study conducted by University of California Davis researchers on another highly contagious animal disease, Foot and Mouth Disease Virus (FMD), determined that effective early detection will avoid dramatic losses to both livestock and the economy. The study concluded that "the median economic impact of an FMD outbreak in California was estimated to result in national agriculture welfare losses of \$2.3 to \$69.0 billion as detection delay increased from 7 to 22 days, respectively". The study also determined that the economic impact of a one-day delay in diagnosis and notification in California would be \$8.1 million, with economic impacts of \$60.7 million and \$197.1 million for a two or three-day delay.

On average, CAHFS conducts 26 necropsies (animal autopsies), processes 910 samples, and runs 2,498 tests to diagnose disease in livestock and poultry each day. This information is provided to veterinarians and owners to determine the appropriate treatment options (such as bacterial antimicrobial resistance results which might influence the decision to treat with antibiotics, toxicology results to identify toxins such as melamine, etc.) and to identify foreign animal disease (Avian Influenza, FMD, vND, etc.) outbreaks before they spread. Testing generates an enormous amount of information (case reports, notes, sample results, photographic evidence) which must be stored and, when appropriate, transmitted to CDFA by CAHFS' LIMS. CAHFS current LIMS can no longer perform this function and is in need of replacement. The following are some operational and functional deficiencies of the LIMS:

System Maintenance and Development Concerns

CAHFS' LIMS is no longer supported by the vendor and is based on inefficient and outdated design principles. The system was developed with technologies dependent on using old software (Microsoft Internet Explorer and Windows 7). Support for Windows 7 ends in January 2020, which means that security updates will no longer be provided. Since LIMS is dependent on Microsoft Internet Explorer, CAHFS IT staff completed validation of the existing system for use with Microsoft Windows 10 during the Fall of 2019. This temporary fix will allow CAHFS to use the existing, obsolete system until a new LIMS, which will not be browser specific, is identified and procured.

LIMS was designed so that some of the processing occurs remotely on the server, while other data is processed on the local computer which results in timeout errors and process inefficiencies. For example, LIMS users in laboratory locations far from the headquarters at UC

Davis experience noticeable delays when using the system. This is extremely outdated and inefficient as new systems are cloud-based. This results in CAHFS employees, who use LIMS daily, having less time available to run mission-critical tests, examine animals with potentially economically devastating diseases, and communicate their findings to CDFA, USDA and other key stakeholders.

Deficiencies in Reporting and Trend Analysis

The current LIMS does not produce the operational reports available in more modern systems that would allow for improved resource management and decision making. Generating reports and retrieving data from the current LIMS is a problematic and time-consuming manual process. The number of reports included with the LIMS are limited, and the ability to generate ad hoc reports requires a special request to IT to develop the query. CAHFS staff responds to at least five new report requests per week, which typically takes an average of 60 hours per report to complete. The system also lacks the data management framework needed to support current bioinformatics and business intelligence strategies needed for standard information management infrastructure; and, it lacks the ability to utilize tools that would make it easier to perform operational planning and analyze diagnostic data for anomalies and epidemiological patterns.

This limits the ability of CAHFS' to provide CDFA with trending disease diagnosis information to effectively perform its mission, identify changes in testing trends to respond to changing client needs, and manage resources effectively. For example, when CDFA requested a county-level map showing where backyard poultry surveillance for Highly Pathogenic Avian Influenza was occurring, it took nearly a month of work to fulfill the request. In the event of an animal or food safety emergency disease outbreak, every hour is critical. As previously noted, a time lag like this can result in severe economic and consumer confidence consequences.

Inability to Exchange Data with Testing Equipment

CAHFS currently performs lengthy, labor-intensive manual coding to enable laboratory equipment to share information with LIMS so that results from testing equipment can be downloaded into LIMS (rather than manually enter data). Due to the ever-changing nature of technology, new equipment needs to be regularly integrated. Laboratory staff must continue to manually enter results from 25 different pieces of laboratory equipment wasting time that could be spent on higher level tasks and decreasing the turnaround time of test results.

CAHFS estimates that in its testing sections in Davis (Toxicology, Molecular Testing, Bacteriology, and Immunology), which run hundreds of tests per day, technicians spends on an average a total of 40 hours per week hand-entering data because the lab equipment is not linked to the LIMS. This amounts to approximately 2,000 hours per year of unnecessary data entry and staff time not spent on higher-level tasks.

Mobile and Wireless Technology Limitations

LIMS does not support non-Windows platforms which prevents CAHFS from implementing modern efficiency improvements like deploying mobile devices in the field and within the

laboratory. Furthermore, the current system does not support wireless technologies which are increasingly being utilized in modern laboratory settings. When combined with barcoding technologies, these systems can be more efficient, and provide more accurate data entry and greater mobility within the laboratory. For example, during the current vND outbreak, CAHFS staff manually enter identifications on each sample submitted by AHFFS emergency response field personnel because CAHFS LIMS does not interface with field staff's mobile devices. Manual identification entry takes one minute per sample. CAHFS is currently receiving 80 to 100 samples per day; the 90-minute delay per day caused by hand-entering these identifications affects the timeliness of vND results to CDFA animal disease response staff, and delays processing of routine diagnostic work submitted by California veterinarians and livestock producers.

No Quality Control/Equipment Management and Sample Materials Inventory Capabilities

Currently LIMS lacks an integrated Quality Control (QC) System. To comply with accreditation standards, CAHFS must regularly track equipment, equipment maintenance, temperatures, Standard Operating Procedures and maintain records which should be easily retrievable and auditable. To meet this function, CAHFS is currently utilizing a combination of paper and a legacy SharePoint database which has security issues and no regular back-up for critical data. This system does not allow for easy data analysis to identify trends, equipment replacement needs, or missed requirements (such as preventive maintenance). A modern QC system and equipment module would produce regular reports to assist in this process.

LIMS also lacks an electronic sample material inventory feature, which are available in newer systems. Laboratory managers and supervisors track supplies in excel spreadsheets. For example, staff in each laboratory location spend at least one hour per week manually going through refrigerators and checking the contents against paper sheets to update inventory. Items that are not seen in the refrigerator are re-ordered though they may simply not have been visible. As many reagents and kits expire, manually tracking this information can be time consuming, and if not done properly, leads to waste.

Data Exchange Limitations and Limitations of Online Services

To function effectively, LIMS needs the ability to send and receive electronically submitted information to and from clients; a client web-based portal to allow online, real-time access to test results and findings; and the ability to accept electronically submitted information from CDFA (especially from mobile devices). A LIMS with electronic submission functionality helps mitigate the decline in surge capacity imposed by new programs by reducing the per case receiving workload and improving accuracy of submission data. Currently clients are faxed, emailed, or sent manually generated hard copies of reports, which can be a slow, time-consuming and resource-intensive process. The current system does not allow for online client submission forms, which requires manual data entry when submissions are received. Automating the initial client and sample information would decrease sample processing time, increase accuracy and be more convenient for clients.

LIMS also has limited ability to accept electronically submitted information from CDFA, especially from mobile devices. Electronic submissions require IT staff to build interfaces

between the systems to accept electronically submitted information which is very time consuming. For instance, recent efforts to incorporate CDFA's Milk and Dairy Food Safety dairy sample collection project information into LIMS resulted in CAHFS expending over 3,000 hours of programmer time and 500 hours of management time. Unfortunately, this process must be replicated during animal disease and food safety emergencies to meet the requirements of specific diseases. This significantly hinders the laboratory's ability to prepare for emergency outbreak samples in advance, which affects turnaround time and results in increased data entry errors. This strains CAHFS limited receiving staff resources.

During the current vND emergency outbreak, CAHFS had to redirect staff from other laboratories to its Davis location and hire additional staff for manual data entry of increased sample numbers. This resulted in costly travel, overtime, and salary/benefits costs, as well as delayed emergency response time. This is inefficient, wastes resources, and leads to client dissatisfaction, which could result in decreased submissions to the laboratory and missed opportunities to identify diseases of concern to California. Most diagnostic laboratories in the United States provide these services to clients. AHFSS is also expanding initiatives, such as implementing risk-based inspections for its egg safety program and building baseline information of antimicrobial use in California farms. LIMS' electronic messaging results associated with these initiatives will need to be implemented. Failure to transmit results electronically results in continued reliance on paper results and hand inputting of data multiple times, which causes inherent delays and risks transcription errors.

Continued reliance on an outdated LIMS may also jeopardize CAHFS' accreditation by the American Association of Veterinary Laboratory Diagnosticians (AAVLD). AAVLD requires accredited laboratories to maintain enough resources to conduct disease surveillance and monitoring services. Not only would the loss of accreditation compromise CDFA's enterprise-wide strategy of maintaining laboratory accreditation, it would also result in the elimination of federal funding provided in cooperative agreement funding to CAHFS by the National Animal Health Laboratory Network and eliminate the opportunity to compete for additional future federal funds. It may also result in the inability to leverage resources and participate in key national laboratory networks.

Due to the security risks associated with the current LIMS after support for Internet Explorer ceases and the significant operational concerns, CAHFS has developed a multiyear plan to replace and maintain LIMS. CAHFS currently does not have the capacity to effectively manage a complex IT project of this size. Therefore, contracted consultant services are needed to manage the project, oversee specifications gathering activities, process workflow designs, and assist with the preparation of bid packages.

E. Outcomes and Accountability

Resources allocated to CDFA will be provided to CAHFS, to be expended. Procurement will be in compliance with University of California policies and procedures. The master contract between CAHFS and CDFA provides, "the Veterinary Diagnostic Laboratory System (VDLS) shall be administered with applicable University regulations and procedures." This includes the services of qualified professionals to supplement the expertise of VDLS staff in development or

review of proposals for new procedures, programs or policies. CAHFS will follow a development path consistent with California's Project Approval Lifecycle (PAL) Framework. Consultant services will be secured to:

- Manage the project
- Document existing application
- Perform "as-is" business process documentation
- Document mid-level requirements
- Conduct market research
- Identify solution alternatives
- Recommend solution

These activities are consistent with California's PAL Framework for Stages 1 and 2.

CAHFS will establish a LIMS Governance body to ensure accountability, milestones are met, and the LIMS replacement aligns with the business needs and objectives of both CDFA and CAHFS. The group will include the following CAHFS and CDFA representatives:

- CAHFS Co-Director(s)
- CAHFS Associate Director for Administration
- CAHFS Information Technology Director
- CAHFS User Group Representative
- CDFA AHFSS Assistant Director
- CDFA Chief Information Officer
- CDFA Project Manager

F. Analysis of All Feasible Alternatives

Alternative #1: Approve \$494,000 GF in FY 2020-21 and \$515,000 GF in FY 2021-22 for Phase 1 of the LIMS replacement.

Advantages: This alternative will start the process of replacing CAHFS' LIMS before it is rendered useless due to outdated technology and lack of support. It will allow CAHFS to transition timely to a new LIMS to increase departmental efficiencies, create mechanisms for electronic information exchange in and out of the system to better serve stakeholders, and provide critical resources to allow CAHFS and CDFA to work in partnership to safeguard California's \$11.2 billion livestock and livestock product industry, protecting public health and the food supply.

Disadvantages: This alternative increases the obligation to the General Fund.

Alternative #2: Do not approve \$494,000 GF in FY 2020-21 and \$515,000 GF in FY 2021-22 for Phase 1 of the LIMS replacement.

Advantages: There will be no obligation to the General Fund.

Disadvantages: AHFSS' ability to respond rapidly and efficiently to animal disease and

food safety outbreaks will continue to degrade as LIMS becomes more obsolete as technology continues to advance. CAHFS submissions may decline as the service level and test turnaround times are negatively impacted, jeopardizing the laboratory's ability to rapidly detect an outbreak. A LIMS that allows information-sharing among relevant entities is mission critical and supports effective decision-making, prevents potential disease incursion-spread, and allows for expeditious response to emergencies. The current LIMS is antiquated, lacks key functionality to provide robust animal disease and food safety prevention testing services to CDFA and is no longer supported by the vendor. As such, compromising CAHFS' mission critical ability to be California's early warning system to safeguard public health from foreign animal disease and food borne pathogens common to animals and humans, can have dire and immediate consequences to California's \$11.2 billion livestock and livestock product industry and CAHFS' and CDFA's ability protect public health and the food supply.

Alternative #3: Pursue industry/client funding.

Advantages: There will be no obligation to the General Fund.

Disadvantages: CAHFS already charges client fees associated with non-regulatory diseases to partially offset its operational costs. Further increases to client fees may result in a decline in the sample submission stream, jeopardizing the laboratory's ability to detect and AHFSS' ability to respond to and contain disease outbreaks. Animal disease outbreaks spread rapidly and are high consequence events which pose a direct threat not only to the livestock industry, but to public health and the food supply. This funding request is intended to replace a core component of disease response and management that has direct benefits to the public and safeguard California's \$11.2 billion livestock and livestock product industry. Because these systems provide a general benefit to the state, industry funding is not the most appropriate funding source.

Alternative #4: Pursue funding from the Federal government.

Advantages: There will be no obligation to the General Fund.

Disadvantages: USDA provides funds for animal health emergency response but does not fund state laboratory information systems. Infrastructure grant funding has been decreasing in recent years, with most federal funds being allocated to cover outbreak response efforts and federal fee for service testing.

G. Implementation Plan

In FY 2020-21 CAHFS will utilize contracted professional project services to manage the LIMS replacement project, document CAHFS' existing application, perform an "as is" business process documentation." In 2021-22 will document mid-level requirements, conduct market research, and identify solution alternatives. Based on the Phase 1 analysis, CAHFS will determine next steps which may result in the need for a solution procurement to complete the LIMS replacement project.

H. Supplemental Information

CAHFS will utilize contracted professional services to perform project management, oversee specifications gathering, process workflow design, document mid-level requirements, conduct market research, and identify solution alternatives.

I. Recommendation

CDFA recommends approval of Alternative 1 to provide \$494,000 GF in FY 2020-21 and \$515,000 GF in FY 2021-22 to implement and complete the initial project phase to replace CAHFS LIMS before it reaches the end of its life-cycle. This alternative will provide for the development of a stable, reliable and functional LIMS where program activities are fully integrated, secure and allow for increased departmental efficiencies to better serve stakeholders. This alternative will provide critical resources to allow CAHFS and CDFA to work in partnership to safeguard California's \$11.2 billion livestock and livestock product industry and protect public health and the food supply.

BCP Fiscal Detail Sheet

BCP Title: Laboratory Information Management System for Food Safety Protection, Animal Disease Prevention, and Emergency Response

BR Name: 8570-009-BCP-2020-GB

Budget Request Summary

Operating Expenses and Equipment

Operating Expenses and Equipment	FY20 Current Year	FY20 Budget Year	FY20 BY+1	FY20 BY+2	FY20 BY+3	FY20 BY+4
5340 - Consulting and Professional Services - External	0	494	515	0	0	0
Total Operating Expenses and Equipment	\$0	\$494	\$515	\$0	\$0	\$0

Total Budget Request

Total Budget Request	FY20 Current Year	FY20 Budget Year	FY20 BY+1	FY20 BY+2	FY20 BY+3	FY20 BY+4
Total Budget Request	\$0	\$494	\$515	\$0	\$0	\$0

Fund Summary

Fund Source

Fund Source	FY20 Current Year	FY20 Budget Year	FY20 BY+1	FY20 BY+2	FY20 BY+3	FY20 BY+4
State Operations - 0001 - General Fund	0	494	515	0	0	0
Total State Operations Expenditures	\$0	\$494	\$515	\$0	\$0	\$0
Total All Funds	\$0	\$494	\$515	\$0	\$0	\$0

Program Summary

Program Funding

Program Funding	FY20 Current Year	FY20 Budget Year	FY20 BY+1	FY20 BY+2	FY20 BY+3	FY20 BY+4
6570 - Agricultural Plant and Animal Health; Pest Prevention; Food Safety Services	0	494	515	0	0	0
Total All Programs	\$0	\$494	\$515	\$0	\$0	\$0