Current Major Laboratory Initiatives

The Partnership for Food Protection Laboratory Sciences Workgroup

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APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

Partnership for Food Protection
Federal, State and Local Collaboration

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Introduction

The Partnership for Food Protection (PFP) was established to provide guidance on implementing the necessary infrastructure and food safety strategies essential to building an integrated human and animal food safety system. Confidence in the integrity and scientific validity of laboratory analytical data and acceptance of laboratory analytical data by regulatory agencies remains critical to the success of an integrated system. Integration endeavors include investments in laboratory accreditation, increasing laboratory capacity and capability, and building stronger relationships between the laboratory and regulatory agencies. These efforts provide added value for the mission of protecting the public health by enhancing the quality of data submitted to regulatory agencies.

Current Major Laboratory Initiatives (CMLI) captures information related to current national integration programs that contain a laboratory component. The PFP Laboratory Science Work Group created CMLI to summarize current integration efforts related to networks and capacity building, laboratory quality management systems, and program-specific funding. Food safety professionals can use CMLI as guidance to improve coordination and cooperation among strategic partners and avoid any duplicative efforts. Laboratories can use the document to identify new funding sources, as well as discover opportunities for collaboration among other laboratories or program partners.

The PFP Laboratory Sciences Workgroup intends to update CMLI on a regular basis to reflect changes in integration program initiatives and funding opportunities. Application deadlines vary for each initiative, and some funding opportunities will not be available post-publication. However, this document can aid laboratories and other interested parties in recognizing the scope of integration initiatives and programs available.

Partnership for Food Protection (PFP) Efforts

PFP Laboratory Sciences Workgroup

Goal/Purpose:
Promote consistency and facilitate information sharing through establishing and utilizing national laboratory best practices.

Objectives:

1. Optimize initiatives among strategic partners for the use of best practices, specifically the PFP's laboratory best practices manual, "Food/Feed Testing Laboratories Best Practices Manual (DRAFT)," to prepare human and animal food testing laboratories for accreditation.
   a. Review current PFP Laboratory Best Practices Manual (LBPM)
   b. Establish procedure for maintaining and updating the LBPM
   c. Identify ways to maximize use of the LBPM
   d. Monitor and revise the LBPM as needed
2. Utilize the PFP's laboratory best practices manual (LBPM) and the APHL Data Acceptance White Paper to prepare a checklist of analytical worksheet elements that should be present for a laboratory analysis to be utilized for regulatory action, in a format that facilitates compliance reviews
   a. Review LBPM and the Data Acceptance White Paper to identify appropriate elements
   b. Determine a standard order of analytical elements, ordered for clarity
   c. Work with PFP Compliance group and other appropriate stakeholders to reach concurrence on elements and order
3. Utilize the PFP's laboratory best practices manual "Food/Feed Testing Laboratories Best Practices Manual (DRAFT)" and the APHL Data Acceptance White Paper to prepare a checklist of analytical worksheet elements that should be present for a laboratory analysis to be utilized for regulatory action, in a format that facilitates compliance reviews.
   a. Review LBPM and the Data Acceptance White Paper to identify appropriate elements
   b. Determine a standard order of analytical elements, ordered for clarity
   c. Work with PFP Compliance and Enforcement Workgroup and other appropriated stakeholders to reach concurrence on elements and order.

For more information, visit the PFP Laboratory Science Workgroup website

PFP Information Technology Workgroup

Goal/Purpose:
Promote data standards to improve the ability to share information electronically among strategic partners, including regulators, epidemiologists and laboratorians. Information technology will need to be addressed across all facets of an integrated food safety system (IFSS), including within each of the other goals outlined in the Strategic Plan. The workgroup will define and understand the requirements for developing an integrated electronic information infrastructure by undertaking technical projects to advance a harmonized and compatible IT environment among food safety officials.

Objective:

1. Undertake technical projects that will advance abilities to harmonize a compatible IT environment among food safety officials
    a. Conduct a review of current data exchange standards for sharing and exchanging data between strategic partners
    b. Evaluate the functional utility of FDA's electronic State Access to Field Accomplishment and Compliance Tracking System (eSAF) IT solution
    c. Establish a systematic survey mechanism to measure and track implementation of PFP IT Workgroup products

For more information, visit the PFP IT Workgroup website.

PFP Training and Certification Workgroup

Goal/Purpose:
Provide input into the development of standard curricula and certification programs for regulators that will promote consistency and competency among the IFSS workforce. A national curriculum framework for human and animal food testing laboratories is also in development, led by the International Food Protection Training Institute (IFPTI),the Association of Food and Drug Officials (AFDO), and the Association of Public Health Laboratories. A critical element for IFSS success is having a competent workforce doing comparable work across strategic partners. A national training and certification program will ensure that regulatory and public health activities are being completed to the same standards of proficiency and quality.

Objectives:

1. Develop a pool of subject matter experts (SMEs) comprised of strategic partners to provide input to cultivate a competent workforce through training and certification
2. Provide input on and disseminate the products produced by the 2015 Training Summit
3. Partner with FDA's Office of Training, Education and Development and IFPTI to develop the National Curriculum Standard for Regulatory Enforcement Professionals.
    a. Develop frameworks representing retail and manufactured food, animal food and laboratory competencies

For more information, visit the PFP Training and Certification Workgroup website.

Mutual Reliance Pilots

Goal/Purpose:
Demonstrate how federal, state and local partners can integrate their food safety programs. Pilot states submit laboratory/regulatory data to FDA to assess the potential for data acceptance and regulatory action. The pilots highlight the importance of an IFSS and identify limitations for data acceptance. FDA Office of Partnerships Integration group provides coordination for these pilots.

Objectives:

1. Integrate food safety programs of inspection, laboratory analysis, communications and data sharing
2. Identify obstacles for improvement that can be addressed through the PFP

Laboratories involved: New York Department of Agriculture and Markets and Wisconsin Department of Agriculture, Trade and Consumer Protection

Laboratory-Related Efforts

Human Food Inspection Contract Program

Goal/Purpose:
Under this program, inspections are performed at selected food manufacturers/processors sites to determine compliance with the Federal Food, Drug and Cosmetic (FD&C) Act, state law, or both. Laboratories test food samples and environmental swabs from manufacturing environments under this contract. As of February 2018, 43 states and Puerto Rico have contracts in place with FDA totaling approximately $11.9 million.

Objective:

1. Place major inspectional emphasis on determining:
    a. Significant Good Manufacturing Practices (GMP)
    b. Unsanitary conditions and practices which may render the food injurious to health
    c. Those conditions or practices involved with introduction, lack of controls and/or growth promotion of pathogenic organisms
    d. Conditions which may have caused food to become filthy, putrid, decomposed or contaminated with foreign objects which present a reasonable possibility of causing risk to health

For more information, visit the Human Food Inspection Contract Program website.

Animal Food/Bovine Spongiform Encephalopathy (BSE) Inspection Contract Program

Goal/Purpose:

Under this program, inspections are performed in both licensed and non-licensed animal food establishments using Category II Type medicated articles to make medicated feeds. Inspections are also conducted to ensure compliance to the prohibition of mammalian protein use in ruminant feeds, which can lead to the spread of BSE. As of February 2018, 34 states and 17 FDA Office of Regulatory Affairs (ORA) Field District Offices are involved in the contract program with over $2.7 million in funding.

Objectives:

1. Ensure animal food establishments comply with requirements of 21 CFR 589.2000 (Animal proteins prohibited in ruminant feed) and 21 CFR 589.2001 (Cattle materials prohibited in animal food or feed to prevent the transmission of BSE)
2. Collect and analyze samples for:
    a. Toxins, usually mycotoxins
    b. Potency of medicated feed
    c. Cross-contamination of medicated feed
    d. Prohibited material, mainly ruminant tissue
    e. Pesticides and industrial chemicals
    f. Toxic heavy metals
    g. Microbes

For more information, visit the Program website

Flexible Funding Model - Infrastructure Development and Maintenance for State Manufactured Food Regulatory Programs (U18) (Cooperative Agreement RFA-FD-18-001)

Goal/Purpose: The goal of this cooperative agreement is to advance efforts for a nationally integrated food safety system (IFSS) by supporting Manufactured Food Regulatory Program Standards (MFRPS), Rapid Response Teams (RRT) and Food Protection Task Force (FPTF) programs, as well as special projects. The MFRPS are intended to ensure that State manufactured food regulatory programs develop and maintain best practices for a high-quality regulatory program. Also, the program standards are intended to enhance food safety by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States. Conformance with these program standards will help Federal and State programs better direct their regulatory activities at reducing foodborne illness hazards in plants that manufacture, process, pack, or hold foods. The purpose of the FPTF funding option is to establish and/or support a Food Protection Task Force responsible for promoting the integration of an efficient statewide human and animal food (HAF) protection system that maximizes the protection of the public health. These efforts would include fostering communication, education, outreach, cooperation and collaboration. The purpose of the RRT FOA section is to facilitate long-term improvements and innovation to the national integrated food safety system by unifying and coordinating federal/state/local HAF emergency response efforts. Standard 10 of the MFRPS requires that the State program have access to a laboratory that has the capacity and capability to analyze collected samples, including food, environmental and clinical. The laboratory should be accredited to ISO/IEC 17025:2005 or operate under a documented ISO-like environment with specific requirements.

Objectives:

1. Provide for the collection of samples (FDA regulated products only) to support laboratory capacity development and product surveillance. Demonstrate the ability to perform any enforcement or other follow-up activities based on sample results
2. Sampling plans will be developed in cooperation with the laboratory to support the objectives of both programs
3. The RRT Program supports development and maintenance/continued operations of multi-jurisdictional, multi-disciplinary RRTs for program improvement and requires extensive cooperation and coordination among State programs (food and feed regulatory, laboratory, epidemiology, emergency management) and their corresponding FDA District Office
4. Incident response and surveillance work conducted by the RRT, including sample collection and laboratory analyses, are considered within scope for this funding option
5. The FPTF will provide a forum for all the stakeholders of the state food protection system—regulatory agencies, academia, industry, consumers, state legislators, Boards of Health and Agriculture, and other interested parties to improve food safety and defense

For more information about the Standards and which states are involved in the MFRPS Cooperative Agreement Program, visit the MFRPS website.

For more information about the ISO/IEC 17025:2005 Cooperative Agreement Program, visit the FDA website.

For more information, please visit the Rapid Response Teams website.

Conformance with the Animal Feed Regulatory Program Standards (AFRPS) (Cooperative Agreement RFA-FD-15-021)

Goal/Purpose:
To advance efforts for a national IFSS by assisting State feed or animal food regulatory programs to achieve and maintain full implementation of the AFRPS. The AFRPS Cooperative Agreement will provide funding for State feed regulatory programs that maintain an FDA feed safety inspection contract to develop and implement the standards; develop and maintain best practices; enhance feed safety; and better direct their regulatory activities towards reducing foodborne illness attributed to feed safety hazards in facilities that manufacture, process, pack, or hold animal feed materials and supplies. Standard 10 of the AFRPS requires that the State program have access to a laboratory that supports regulatory functions. The program and laboratory are required to prepare a sample collection and analysis schedule that includes the type(s) of feed to be analyzed, number of samples to be collected, estimated time frame for collection, and type(s) of analysis to be performed.

Objective:

1. Provide laboratories supporting State feed regulatory programs the ability to obtain (Competition B or D) or maintain (Competition C or D) ISO/IEC 17025:2005 accreditation including:
    a. conduct chemical and microbiological analysis of feed samples
    b. produce valid and defensible testing data for possible regulatory action
    c. maintain and enhance feed testing laboratory's capabilities
    d. improve lab capacity for feed supply to further enhance public health
    e. increase sharing of laboratory results
    f. advancement of a nationally integrated feed safety system

For more information, please visit the AFRPS website.

Council to Improve Foodborne Outbreak Response (CIFOR)

Goal/Purpose:
A multidisciplinary working group convened to increase collaboration across the country and across relevant areas of expertise to reduce the burden of foodborne illness in the U.S. CIFOR works to identify barriers to rapid, accurate detection, reporting and investigation of foodborne disease outbreaks.

Objectives:

1. Improve laboratory methods at the local, state and federal levels to detect, investigate, control and prevent foodborne disease outbreaks
    a. Identify and address barriers that impede laboratory response to foodborne illness
2. Through a multidisciplinary working group, develop and share guidelines, processes and products that will facilitate food foodborne outbreak response, including:
    a. CIFOR Guidelines for Foodborne Disease Outbreak Response
    b. CIFOR Toolkit
    c. Outbreaks of Unknown Etiology (OUE) Guidelines

For more information, including a breakdown of the various workgroups, visit the CIFOR website.

Regulatory Human and Animal Food Laboratory Professionals Curriculum Framework

Goal/Purpose:

This competency-based training curriculum framework is intended to standardize the knowledge of laboratory professionals performing regulatory human and animal food testing. A workgroup of subject-matter experts developed the framework based on the core competencies needed to perform laboratory testing effectively. In early 2018, a new funding opportunity announcement was released to continue the development of the Laboratory Curriculum Framework (RFA-FD-18-005).

Objectives:

1. The framework will help laboratories
   a. Identify training gaps
   b. Catalog existing training courses/modules
   c. Inform training curricula
   d. Ensure consistent performance expectations
   e. Increase confidence in laboratory test results
2. The framework will create career-spanning professional development learning paths through five professional levels (entry, mid-level, expert, supervisor/manager and senior administration) across four competency domains (technical, communication, programmatic and leadership)
3. A blended learning curriculum based upon the framework will be developed

For more information, visit APHL's website, the JAOAC article on the curriculum framework or the 2018 Funding Opportunity Announcement.

Laboratory Quality Management System Efforts

ISO/IEC 17025:2005 Accreditation for State Food Testing Laboratories (Cooperative Agreements RFA- FD-15-023)

Goal/Purpose:
The intended outcome of this Funding Opportunity Announcement is for microbiological and chemical food analyses performed on behalf of State manufactured food regulatory programs to be conducted within the scope of an ISO/IEC 17025:2005 accredited laboratory and the goal of achieving and further advancing a nationally integrated food safety system. This will be accomplished by preparing the primary food testing laboratories for State manufactured food regulatory programs to achieve and maintain ISO/IEC 17025:2005 laboratory accreditation. Currently accredited laboratories will also be prepared for accreditation enhancements. Increased laboratory analyses from ISO/IEC 17025:2005 accredited laboratories accomplished through this cooperative agreement, will in effect serve to increase the analytical capacity for FDA and enhance efforts to protect the food supply.

Objectives:

1. Perform initial quality management system assessment and gap analysis
2. Monitor progress through on-site visits, conference calls, emails, and other correspondence
3. Provide FDA training and assistance (technical and financial) to apply, maintain, and enhance laboratory accreditation
4. Perform final assessment of laboratory quality management systems

For more information, visit the ISO CAP website.

Maintenance and Enhancement of ISO/IEC 17025 Accreditation and Whole Genome Sequencing for State Food Testing Laboratories (Parts A & B) (Cooperative Agreement RFA-FD-17-010)

Goal/Purpose:
The intended outcome of this cooperative agreement is to advance the goal of a national integrated human and animal food safety system by supporting and enhancing state human food laboratory activities.

Objectives:

1. Ensuring microbiological and chemical food analyses performed on behalf of the State manufactured food regulatory programs are conducted within the scope of an ISO/IEC 17025 accredited laboratory
2. Strengthening the collaboration between the laboratories and State manufactured food regulatory programs
3. Increasing the number of State samples collected and analyzed for surveillance purposes annually
4. Developing a stronger international rapid surveillance system for pathogen trace back through the GenomeTrakr network using a minimum set of metadata fields for all food and environmental isolates

For more information, visit the ISO CAP website

Implementation of the Animal Feed Regulatory Program (AFRPS) (Cooperative Agreement RFA-FD-15-021)

Goal/Purpose:
The intended outcomes of this cooperative agreement is to advance the goal of a national integrated human and animal food safety system by supporting and enhancing state animal food laboratory activities.

Objectives:

1. Ensuring microbiological and chemical food analyses performed on behalf of the State manufactured food regulatory programs are conducted within the scope of an ISO/IEC 17025 accredited laboratory
2. Strengthening the collaboration between the laboratories and State animal food regulatory programs
3. Provide funding and resources for laboratories that support animal feed programs and are pursuing accreditation to the ISO/IEC 17025 laboratory

For more information, visit the AFRPS CAP website.

Maintenance and Enhancement of ISO/IEC 17025 Accreditation and Whole Genome Sequencing for State Food Testing Laboratories (Part C) (Cooperative Agreement RFA-FD-17-010)

Goal/Purpose:
Grant awarded to APHL to assist the non-FDA funded State laboratories with increased readiness for ISO/IEC 17025 accreditation, to assist FDA in the development of training courses, workshops, educational materials, and meetings in support of laboratory accreditation, whole genome sequencing and GenomeTrakr, and improved eLEXNET data sharing and collaboration through outreach, marketing and workgroup support.

Objectives:

1. Aid local and state laboratories in obtaining/expanding accreditation to the ISO/IEC 17025:2005 Standard by creating a community of practice and providing resources and opportunities for peer-to-peer exchange of information
2. Staff, manage and/or contribute to the following workgroups/initiatives:
   a. Food and Feed Testing Subcommittee
   b. eLEXNET outreach activities
   c. Accreditation Discussion Board
   d. Website Resource repository
   e. Development and web repository of training webinars, including accreditation and GenomeTrakr topics
   f. Direct assistance for unfunded laboratories
   g. Governmental Human and Animal Food Laboratory Accreditation Meeting
   h. Genome Trakr in person meeting

For more information, visit the APHL Laboratory Accreditation website.

Meat and Poultry Inspection "At Least Equal To" Cooperative Agreement

Goal/Purpose:
Under an "at least equal to" cooperative agreement with USDA-FSIS, states may operate their own Meat and Poultry Inspection (MPI) Programs for intrastate commerce if they meet and enforce requirements "at least equal to" those imposed under Federal laws. The state MPI programs should update and maintain their laboratory microbiological and chemical detection methods so they are "at least equal to" the applicable FSIS guidebook methods. Cooperative agreements are available for laboratories looking to participate in the USDA MPI program.

Objectives:

1. States will enforce requirements "at least equal to" those imposed under:
   a. Federal Meat Inspection Act
   b. Poultry Products Inspection Act
   c. Humane Methods of Slaughter Act of 1978
2. State programs will have product sampling and laboratory methods with capabilities and safeguards that are "at least equal to" FSIS's sampling and analysis methods
   a. FSIS integrated ongoing documents and on-site reviews of applicable analytical methods in annual comprehensive reviews of state MPI programs
   b. Determination of state program's conformance to the "at least equal to" requirements will be determined by FSIS

For more information, visit the USDA MPI Program website or review the Compliance Guidelines.

FSIS Accredited Laboratory Program (ALP)

Goal/Purpose:
The ALP accredited non-federal analytical chemistry laboratories to analyze meat and poultry food products for moisture, protein, fat and salt content and/or certain classes of chemical residues. Currently, specific chemical residues are chlorinated hydrocarbons (CHC), polychlorinated biphenyls (PCB), sulfonamides, nitrosamines and arsenic. The ALP is accredited to the ISO 17043 standard as a proficiency testing (PT) provider and administers PT sample events in support of this program.

Objectives:

1. When accredited, the analytical laboratory may be used in lieu of an FSIS laboratory for analyzing official regulatory samples
2. Requirements for accreditation include, but are not limited to:
   a. Adequate facilities and equipment
   b. Personnel qualifications and demonstrated capabilities
   c. Sample control, sample integrity
   d. Records management
   e. Use of official and approved analytical methods
   f. Participation in Proficiency Testing Programs
   g. Random on-site review and audit of facilities

For more information about the ALP, visit FSIS's website or view a listing of accredited laboratories.

Laboratory Networks and Capacity Building Efforts

Food Emergency Response Network (FERN) (Cooperative agreements RFA-FD-15-019; USDA-FSIS-03102015)

Goal/Purpose:
The FERN cooperative agreements are intended to target state, local and tribal FERN laboratories to provide increased analytical microbiological, chemical and radiological capacity and expertise in the event of food outbreaks/large-scale food emergency events requiring surge capacity testing of implicated food samples. These samples could involve foods and/or environmental samples related to foods, and will be collected by federal, state or local agencies. Selected laboratories with potential sample collection capabilities may be tasked with sample collection activities in support of this program. Numbers of samples and scheduling of samples will be determined by the FERN National Program Office (NPO) in coordination with grantees. Federal or state surveillance assignments will also be a source of samples for laboratory analysis. Each laboratory should have a quality management system in place to ensure data quality. Laboratories will be encouraged to obtain ISO/IEC 17025 accreditation or adopt a quality system comparable to this international standard.

Objectives:

1. Provide testing capacity and subject matter expertise (including method development and validation) in the event of a food outbreak or emergency
2. Implement protocols to provide standardized analytical results through the usage of standardized methods, equipment platforms, analytical worksheets and electronic reporting
3. Selected laboratories with potential sample collection capabilities may be tasked with sample collection activities
   a. Samples could involve foods and/or environmental samples related to foods
   b. Samples not collected by the laboratory will be collected by federal, state or local agencies
   c. Samples collection will be documented and tracked using chain-of-custody procedures
4. Laboratories will be involved in small-scale, short-term method development and method validation plans

For more information, visit the FERN website.

Laboratory Response Network (LRN) (Cooperative Agreement RFA-TP12-120102)

Goal/Purpose:
Established by the Department of Health and Human Services and CDC, the LRN is a national network of more than 150 local, state and federal public health, food testing, veterinary diagnostic, and environmental testing laboratories that provide the laboratory infrastructure and capacity to respond to biological and chemical threats and other public health emergencies.

Objectives:

1. Improve the public health infrastructure to increase laboratory capacity
2. Develop, maintain and strengthen an integrated domestic and international network of laboratories
3. Respond quickly to biological, chemical and radiological threats and other high priority public health emergencies needs through training, rapid testing, timely notification and secure messaging of laboratory results

4. Emphasize local laboratory bioterrorism preparedness and response by:
    a. Increasing the number of trained laboratory workers in state and local public health facilities
    b. Distributing standardized test methods and reagents to local laboratories
    c. Promoting the acquisition of advanced technologies
    d. Supporting facility improvements

For more information, visit the LRN website.

FDA Center for Veterinary Medicine (CVM) Veterinary Laboratory Investigation and Response Network (Vet-LIRN) Veterinary Diagnostic Laboratory Program (Cooperative Agreement PAR-17-141)

Goal/Purpose:

The Vet-LIRN cooperative agreements are intended to provide increased sample analyses in the event of animal food or drug related illnesses or other large-scale animal food or drug related illnesses or other large-scale animal food/feed emergency events requiring surge capacity testing of implicated diagnostic or animal food samples.

Objectives:

1. Enable analyses during CVM investigations of consumer complaints or in the event that surge capacity is needed by FDA for analyses for potential microbiological or chemical contamination. Samples may include:
    a. Animal diagnostic necropsy or clinical samples
    b. Environmental samples related to animal/food/feed/drug production
2. Perform examinations of veterinary diagnostic samples, which:
    a. Facilitates early detection of animal food/drug adulteration or contamination
    b. Contributes to overall food safety, as animal food events could signal potential issues in the human food system
3. Facilitate method standardization, training and proficiency testing of partner laboratories, which strengthens the overall food safety system by developing increased capacity and capabilities to detect adulteration which could affect animals raised for human consumption or companion animals. Samples could involve:
    a. Animal food/feed/drugs
    b. Environmental samples related to animal food/feed drug production
    c. Animal diagnostic necropsy or clinical samples

For more information, please visit the Vet-LIRN website.

Vet-LIRN Network Capacity-Building Projects (Cooperative Agreement PAR-18-604)

Goal/Purpose:
To support enhanced human and animal food safety by strengthening the capacity, collaboration, and integration of food-safety laboratories and networks, thereby facilitating an effective and coordinated response to future human and animal food safety issues; for research related to emerging public food safety issues identified by the Vet-LIRN network office, for equipment and personnel necessary to expand laboratory capability and capacity, and for other related activities. Intended to build domestic laboratory capacity as put forth in the Food Safety Modernization Act (FSMA), by developing the Vet-LIRN laboratory Network capabilities and capacity to investigate potential animal foodborne illness outbreaks.

Objectives:

1. Facilitate research activities that are needed to adapt to current and emerging testing needs
2. Allow the network to leverage emerging technologies such as whole genome sequencing to be used during epidemiologic tracebacks and case investigations related to foodborne illness outbreaks
3. The results of Network testing can provide real time data on emerging animal food safety and public health pathogens needed for the Agency to make informed regulatory decisions

National Animal Health Laboratory Network (NAHLN)

Goal/Purpose:
The NAHLN supports US animal agriculture by developing and increasing the capabilities and capacities of a national veterinary diagnostic laboratory network to support early detection, rapid response, and appropriate recovery from high-consequence animal diseases. It is a nationally coordinated network and partnership of Federal, State, and university-associated animal health laboratories. NAHLN veterinary diagnostic laboratories provide animal health diagnostic testing to detect biological threats to the nation's food animals, thus protecting animal health, public health, and the nation's food supply. They provide the capability to diagnose both endemic and high-consequence livestock pathogens in animals, food, and environmental samples and are likely to be the first-line laboratories for recognition of an intentionally or accidentally introduced agent in animals.

Objectives:

1. Maintain the capability and capacity to provide nationwide laboratory services in support of early detection and response to foreign animal disease outbreaks or other adverse animal health events
2. Provide national diagnostic laboratory quality management system training
3. Establish and maintain uniformly trained and competent animal disease diagnostic laboratory personnel
4. Provide national animal disease diagnostic technical proficiency testing
5. Support the development, validation, and deployment of critical animal disease diagnostic testing methods through research and data exchange
6. Evaluate animal health emergency preparedness through scenario testing to identify and prioritize testing and communication gaps
7. Assess the health and well-being of the country's livestock population through active and passive diagnostic surveillance testing for exotic, emerging, and zoonotic diseases of animals

For more information, visit the NAHLN website.

Antibiotic Resistance Laboratory Network (ARLN)

Goal/Purpose:
This network, established by CDC, is comprised of seven regional laboratories that work to detect and support response to resistance organisms collected from clinical specimens. These laboratories will work to detect existing and emerging types of antibiotic resistance, investigate emerging resistance more quickly and effectively, and work to prevent and combat future resistance threats.

Objectives:

1. Regional laboratories will perform core testing for their region, including:
   a. Molecular testing to detect colonization of carbapenem-resistant *Enterobacteriaceae* (CRE) threat assessments
   b. Special threat assessments by request on new or known threats, such as multi-resistant *Pseudomonas aeruginosa* (MRPA), vancomycin-resistant *Enterococci* (VRE) and vancomycin-resistant *Staphylococcus aureus* (VRSA)
   c. Isolate collection for use in CDC's Antibiotic Resistance Isolate Bank and whole genome sequencing projects
2. Select laboratories will provide additional testing to support nationwide needs, including:
   a. Fungal susceptibility of *Candida* species to identify emerging resistance
   b. *Clostridium difficile* special projects
   c. Increased testing of *Neisseria gonorrhoeae* for antimicrobial susceptibility
   d. Reflex Culture pilot with *Salmonella* and Enterotoxigenic *E. coli* (ETEC)
   e. Antimicrobial susceptibility and serotyping of multidrug-resistant *Streptococcus pneumoniae*

For more information, visit the ARLN website.

Integrated Consortium of Laboratory Networks (ICLN)

Goal/Purpose:
To create the basis for a system of laboratory networks capable of integrated and coordinated response to and consequence management of terrorism, and other major incidents requiring laboratory capabilities by chartering two major interagency groups.

Objectives:

1. Joint Leadership Council (JLC)
   a. Comprised of senior leadership members from each of the nine signatory agencies
      - ◊ Department of Agriculture
      - ◊ Department of Defense
      - ◊ Department of Energy
      - ◊ Department of Health and Human Services
      - ◊ Department of Homeland Security
      - ◊ Department of the Interior
      - ◊ Department of Justice
      - ◊ Department of State
      - ◊ Environmental Protection Agency

   b. Charged with assuring the appropriate strategies are in place to support an effective all-hazard laboratory response capability

2. Network Coordinating Group (NCG)
   a. Composed of representatives from signatory departments and the operational leaders of the individual laboratory networks
   b. Charged with promoting enhanced commonality and integration of network functions

For more information, please visit the ICLN website.

GenomeTrakr Network

Goal/Purpose:
Established by the FDA in late 2012, this network of food safety laboratories collects and sequences genomes of foodborne pathogens to speed illness outbreak investigations and reduce foodborne illnesses and deaths.

Objectives:

1. Utilize whole genome sequencing for pathogen identification
   a. House the data in public databases at the National Center for Biotechnology Information (NCBI)
   b. Provide real-time comparison and analysis

2. Subproject: Minnesota/Washington/New York/FDA Real-Time *Salmonella* Enteritidis Project
   a. State laboratories in these states have partnered with FDA to conduct real-time sampling of *Salmonella* Enteritidis isolates from clinical, food and environmental samples
   b. Genomic sequences and corresponding collection information for the samples are publicly available in the GenomeTrakr database maintained by NCBI

For more information, visit the GenomeTrakr Network website.

PulseNet (The National Molecular Subtyping Network for Foodborne Diseases)

Goal/Purpose:
Since 1996, CDC's PulseNet has been used to compare DNA fingerprinting profiles to detect and define clusters of bacterial foodborne pathogens such as *Salmonella*, *Listeria* and *E. coli* O157. Laboratorians are certified to participate in PulseNet. Laboratorians, epidemiologists and environmental health specialists in foodborne surveillance activities work together to identify outbreaks and determine causes of foodborne illness.

Objectives:

1. Detect and define foodborne outbreaks
    a. Leads to prevention opportunities and continuous improvements in our food safety system that might not otherwise have occurred
2. Subproject: Real-time *Listeria* Project
    a. Comparing PFGE DNA fingerprints with whole genome sequencing
    b. Apply lessons from Listeria to further transform outbreak detection and response for other priority foodborne infections (i.e. *Salmonella* and *E. coli*)
    c. New techniques enable CDC to provide partners the information they need to be more confident in their food safety decisions, including:
        i. Regulatory action and enforcement
        ii. Recalls
        iii. Changes in manufacturing and processing
        iv. More precise consumer messaging during outbreaks

For more information, visit the PulseNet website. Also available is a presentation on the real-time Listeria whole genome sequencing project.

CaliciNet (National Norovirus Outbreak Network)

Goal/Purpose:
CDC launched CaliciNet in 2009 to collect information on norovirus strains associated with gastroenteritis through a national surveillance network of local, state and federal public health laboratories. Laboratories are certified to participate in CaliciNet. There are several CaliciNet Outbreak Support Centers in California, Idaho, New York, Tennessee and Wisconsin.

Objectives:

1. Collect electronically submitted data from public health laboratories, including:
    a. Genetic sequences of norovirus strains
    b. Epidemiology data from norovirus outbreaks
2. Compare norovirus strains with other strains in the database, helping CDC in their efforts to:
    a. Link outbreaks to a common source
    b. Monitor norovirus strains that are circulating
    c. Identify newly emerging norovirus strains

For more information, visit the CaliciNet website.

The Foodborne Diseases Active Surveillance Network (FoodNet)

Goal/Purpose:
Conduct population-based active surveillance for laboratory-confirmed infections caused by several bacterial and parasitic pathogens. FoodNet is a collaborative program among CDC, FDA, USDA-FSIS, and 10 state health departments. FoodNet protects public health through surveillance, surveys (laboratories, physicians, and the general population) and population-based epidemiological studies.

Objectives:

1. Track important illnesses commonly transmitted by food
2. Generate information used to guide and monitor food safety efforts by:
   a. Estimating numbers of foodborne illnesses
   b. Monitoring changes in incidence of specific illnesses over time
   c. Attributing illnesses to specific sources and settings
   d. Disseminating information to appropriate parties
3. Conduct active surveillance for the following bacterial pathogens:
   a. *Campylobacter*
   b. *Listeria monocytogenes*
   c. *Salmonella*
   d. *Yersinia*
   e. Shiga toxin-producing *E. coli* (STEC)
   f. *Shigella*
   g. *Vibrio*
4. Conduct active surveillance for the following parasitic pathogens:
   a. *Cyclospora*
   b. *Cryptosporidium*

For more information, visit the FoodNet website.

National Antimicrobial Monitoring System (NARMS) for Enteric Bacteria

Goal/Purpose:
NARMS is a collaboration among state and public health departments, along with federal agencies, to create a national public health surveillance system that tracks changes in the antimicrobial susceptibility of certain enteric bacteria. Laboratories test samples from ill persons, retail meats from grocery stores and farm animals to track antibiotic resistance.

Objectives:

1. Track changes in the antimicrobial susceptibility of enteric bacteria found in ill persons (CDC), retail meats (FDA) and food animals (USDA), including:
    a. *Salmonella*
    b. *Campylobacter*
    c. *Shigella*
    d. *E. coli* O157
    e. *Enterococcus*
    f. *Vibrio* (other than *V. cholerae*)
2. Protect public health by providing information about:
    a. Emerging bacterial resistance
    b. Pathways by which resistance is spread
    c. Differences between resistance and susceptible infections

For more information, visit the NARMS website.

CryptoNet (Molecular-based Tracking to Better Understand U.S. Cryptosporidiosis Transmission)

Goal/Purpose:
In response to the inability of traditional clinical diagnostics to distinguish *Cryptosporidium* species, genotypes, and subtypes and increased national reporting of cryptosporidiosis, CDC developed CryptoNet, the first molecular tracking system for a parasitic infection. CryptoNet is a multidisciplinary, molecular-based surveillance system built on the common BioNumerics platform successfully used by PulseNet and CaliciNet.

Objectives:

1. Facilitate real-time sharing of molecular epidemiology data among U.S. national, state, and local public health departments
2. Elucidate the epidemiology of cryptosporidiosis and *Cryptosporidium* species, genotype, and subtype transmission by:
    a. Improving detection, investigation, and interpretation of waterborne, zoonotic, person-to-person, and foodborne cryptosporidiosis outbreak data
    b. Identifying geographic and temporal changes in the distribution of *Cryptosporidium*
    c. Increasing capacity to identify traditional and novel epidemiological links and risk factors, outbreak sources, and sources of contamination identifying *Cryptosporidium* species, genotypes, and subtypes not previously known to infect humans

For more information, visit the CryptoNet website.

Norovirus Sentinel Testing and Tracking (NoroSTAT) Network

Goal/Purpose:
NoroSTAT is a collaborative network of seven state health departments and CDC working together to establish and maintain standard practices for norovirus outbreak reporting to CDC's National Outbreak Reporting System (NORS) and CaliciNet.

Objectives:

1. Improve timeliness, completeness and consistency of norovirus outbreak reporting to NORS and CaliciNet
2. Enhance communication among epidemiologists and laboratorians in state health departments and CDC, enabling timely exchange of information regarding norovirus outbreak surveillance

For more information, visit the NoroSTAT website.

Animal Feed Network – SampleNet

Goal/Purpose:
SampleNet is a system for early notification to share animal feed and pet food laboratory samples considered "adulterated" and assist regulatory programs with surveillance, mitigation and work planning. With the early notification, regulators in the best position to respond will have access to the information as soon as it becomes available.

Objectives:

1. Increase protection of the feed supply and the health of animals
2. Work as a complementary portal to current PETNet and LivestockNet within the Animal Feed Network
3. Organize laboratory data into three primary categories: a. Product information b. Laboratory information c. Sample results
4. Use sample information for emergencies, national surveillance and work planning of members' own feed regulatory programs

For more information, visit the SampleNet website.

Vet-LIRN Cooperative Agreement Program to Expand and Validate Testing Methods for Food Contaminants in Animal Diagnostic Specimens (Cooperative Agreement PA-13-244)

Goal/Purpose:
Expand and validate detection methods among Vet-LIRN cooperative agreement laboratories.

Objectives:

1. Add insight into investigations not routinely obtained from traditional food testing laboratories through testing of diagnostic specimens
2. Increase the suite of validated methods available for testing during outbreaks or events in organs and diagnostic samples (urine, feces, etc.) that are not typical food matrices

3. Strengthen collaborations and integration of network laboratories to encourage seamless interactions during actual emergency-related testing

For more information, visit the Vet-LIRN website.

Electronic Laboratory Exchange Network (eLEXNET)

Goal/Purpose:
This integrated, secure network allows health officials from multiple government agencies to compare, communicate and coordinate findings of laboratory analyses in real time. eLEXNET enables health officials to assess risks, analyze trends and detect potentially hazardous foods more quickly.

Objectives:

1. Streamline and improve food safety testing efforts through increased data sharing and collaboration
2. Enable laboratories to access centralized "one-stop" collaboration platforms that integrate and index information across disparate food safety networks to provide relevant information and actionable content
3. Enhance support for real-time outbreak response using integrated data analytics and information sharing tools that link across regulatory actions, lab findings and external data sources to reveal food safety signals
4. Involve Federal, state and local food safety partners in establishing standards for food safety elements, test methods, data sharing and electronic data submission
5. Disseminate information on the effectiveness of food-related test methods

For more information, visit the eLEXNET website.

Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE)

Goal/Purpose:
With support from CDC, USDA and APHL, FoodCORE centers work together to develop new and better methods to detect, investigate, respond to, and control multistate outbreaks of foodborne diseases. Efforts are primarily focused on outbreaks caused by bacteria, including Salmonella, Shiga toxin-producing Escherichia coli (STEC), and Listeria. The ability to detect and investigate viral and parasitic foodborne disease outbreaks will also be strengthened.

Objectives:

1. Enhance public health laboratory surveillance
2. Conduct epidemiologic interviews and investigations
3. Perform environmental health assessments
4. Develop best practices and replicable models for detection, investigation, response, and control efforts
5. Provide data about the burden, timeliness and completeness of foodborne disease activities

For more information, visit the FoodCORE website.

Integrated Food Safety Centers of Excellence (COEs)

Goal/Purpose:
Established Centers identified by CDC train other health departments by developing and providing online and in-person resources, and assistance for foodborne illness detection, surveillance and investigation. They serve as a resource for public health professionals at state, local and regional levels.

Objectives:

1. Strengthen surveillance and outbreak investigations
2. Analyze timeliness and effectiveness of responses
3. Train public health staff in proven investigation techniques
4. Educate future food safety workforce
5. Improve capacity of information systems
6. Evaluate and communicate best practices

For more information, visit the COE website.

Program-Specific Funding Lines

Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) - Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity in State and Local Health Departments (Cooperative agreement CDC-RFA-CK14-140102PPHF15)

Goal/Purpose:
To provide state, local and territorial health department grantees with financial and technical resources to build and strengthen epidemiology, laboratory and health information systems capacity as part of CDC's national funding strategy to respond to domestic infectious disease threats.

Objectives:

1. Strengthen epidemiologic capacity
2. Enhance laboratory practice
3. Improve information systems
4. Develop and implement prevention and control strategies

For more information, visit the ELC website.

Pesticide Data Program

Goal/Purpose:
The USDA's Pesticide Data Program (PDP) is a national pesticide residue monitoring program that produces the most comprehensive pesticide residue database in the U.S.

Objectives:

1. Administer sampling, testing and reporting of pesticide residues on agricultural commodities in the U.S. food supply, with an emphasis on those commodities highly consumed by infants and children
2. Provide data that will:
   a. Enable EPA to assess dietary exposure
   b. Facilitate the global marketing of U.S. agricultural products
   c. Provide guidance for FDA and other governmental agencies to make informed decisions

For more information, visit the PDP website.

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Cooperative Agreements

Goal/Purpose:
The goal of the National Pesticide Program, consistent with FIFRA, is to assure that pesticides are made available for use and are properly sold, distributed and used in a way that is protective of human health and the environment. FIFRA cooperative agreements provide funding and support to laboratories performing the testing.

Objectives:

1. Protect people and ecosystems that may be exposed to pesticides through:
   a. Pesticide product registration and review program
   b. Outreach
   c. Technical assistance
   d. Compliance and enforcement programs
2. Achieve protective outcomes through collaborative efforts from:
   a. Citizens and pesticide users
   b. States, tribes, territories and regions
   c. Office of Pesticide Programs
   d. Office of Enforcement and Compliance Assistance
   e. Other partners
3. Enable States, Tribes and Territories to serve as EPA's "eyes and ears" on the ground to:
   a. Identify pesticide concerns
   b. Provide EPA feedback from the field to determine if intended risk mitigation measures are effective
   c. Monitor compliance with the regulated community
   d. Take appropriate enforcement action when necessary

For more information, visit the FIFRA website.

Grade "A" Milk Safety and Molluscan Shellfish Cooperative Agreement Program

Goal/Purpose:
The goal of the State Cooperative Programs Grants for National Grade "A" Milk Safety Programs and National Shellfish Sanitation Programs (the Milk and Shellfish Grant Program) is to provide funds for training and equipment purchases in support of milk and shellfish regulatory programs. FDA provides this grant program in collaboration with the National Conference on Interstate Milk Shipments (NCIMS), the Interstate Shellfish Sanitation Conference (ISSC), and the Association of Food and Drug Officials (AFDO).

Objectives:

1. Support state, tribal and territorial Grade "A" milk safety and molluscan shellfish regulatory programs to participate in technical training, including various FDA-supported Grade "A" milk training courses, FDA-supported shellfish training courses, milk or shellfish seminars, and Laboratory Evaluation Officer (LEO) milk or shellfish training courses
2. Provide equipment to assist the states, tribes and territories with the implementation of their Grade "A" milk safety and/or shellfish sanitation programs

For more information visit FDA's Grade "A" Milk Safety and Molluscan Shellfish CAP website.

Grade "A" Pasteurized Milk Ordinance (PMO)

Goal/Purpose:
The Grade "A" PMO is a recommended standard for legal adoption by States, counties and municipalities in order to encourage greater uniformity and a higher level of excellence of milk sanitation practices in the U.S.

Objectives:

1. As a recommended standard, facilitate the shipment and acceptance of milk and milk products of high sanitary quality in interstate and intrastate commerce
2. Prescribe chemical and bacteriological sampling and laboratory testing procedures

For more information, visit the PMO website.

National Shellfish Sanitation Program (NSSP)

Goal/Purpose:
Through this program, the FDA, State regulatory agencies and the shellfish industry work together to keep molluscan shellfish (i.e., oysters, clams and mussels) safe for consumption.

Objectives:

1. Keep molluscan shellfish safe for consumption by adhering to strict controls on their growing, harvesting, processing, packaging and transport
2. Keep contaminated molluscan shellfish out of the marketplace by:
   a. Classifying growing areas based on water quality and other factors that indicate suitability for harvest
   b. Inspecting facilities that handle shellfish to ensure the use of proper sanitary measures
   c. Patrolling to deter illegal harvesting from prohibited waters
   d. Conducting laboratory testing and analysis of shellfish and water samples

For more information, visit the NSSP website and the Interstate Shellfish Sanitation Conference website.

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

Partnership for Food Protection

The Partnership for Food Protection (PFP) is a group of dedicated professionals from Federal, State and Local governments with roles in protecting the food supply and public health. PFP is the structure used to coordinate representatives with expertise in food, feed, epidemiology, laboratory, animal health, environment and public health to develop and implement an Integrated Food Safety System (IFSS). For more information on current major laboratory initiatives, please visit the PFP website.

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