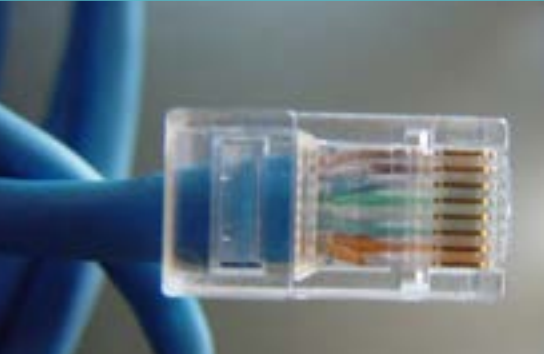


Data Exchange among Food and Feed-Testing Laboratories and FDA's eLEXNET

Discovery
Document



August 2013

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Executive Summary

Food and feed-testing laboratories serve as a significant resource for some of the critical data needed for public health decisions during foodborne and feed-related disease outbreaks. Investigators need all available data as soon as possible for a timely and coordinated outbreak response. Food safety systems have been created so laboratories can exchange and leverage the data needed during an outbreak. The Food and Drug Administration's (FDA) Electronic Laboratory Exchange Network (eLEXNET) is an integrated, secure network that allows agencies in food safety to compare, communicate and coordinate findings of laboratory analyses. Under the current FDA cooperative agreement, APHL is investigating the full automation and creation of standardized data transmission to eLEXNET. This report reflects synthesis information gathered from interviews, existing reports and data exchange manuals, and those with expertise in food and feed data exchange, to identify gaps and suggest next steps to improve food and feed data exchange between state laboratories and FDA.

The exchange of food safety data is rapidly changing. Current FDA and external data initiatives reveal that most of these data exchanges are purpose-built to meet a specific need, and as such, many of them do not support electronic exchange. Also, the initiatives expose intersecting communities, with food safety experts frequently involved in multiple initiatives. In order to ensure an integrated food safety system, these data initiatives will have to work in concert with each other to allow for seamless and interoperable data exchange.

Current food and feed laboratory informatics capabilities highlight significant diversity in testing volume, data exchange capabilities and informatics needs. This variety of technical and systems capabilities is reflected in laboratories data exchange with eLEXNET. Many laboratories are utilizing manual processes or very simple technical systems to manage data. While the technology utilized in these laboratories may be appropriate to the laboratory's needs, it limits the mechanisms that the laboratory can leverage for data exchange. Furthermore, gaps also exist within the eLEXNET system.

eLEXNET is currently used primarily for retrospective studies rather than for early detection and prevention of disease outbreaks. This is primarily due to the limited capacity to accept large files, time consuming manual data entry, insufficient mapping processes, lack of reporting mandates, and lengthy intervals between the completion of testing and the uploading of data. These areas for improvement in the current state laboratory to FDA data exchange will need to be addressed in order to realize the system's full potential.

Moving forward, APHL recommends the following important steps toward improving data exchange between state laboratories and FDA systems.

- Leverage those with expertise in food and feed data exchange to obtain community consensus on planned improvements.
- Identify the minimum data elements required for adequate data exchange.
- Establish data standards for the electronic exchange of food and feed-testing laboratory results.

As these standards are developed, future steps include investigating appropriate transport mechanisms, defining a strategy for increasing the amount of data in the system and planning pilots with laboratories to implement the new standards and transport mechanisms developed. Beyond these challenges, there are significant policy obstacles to address before eLEXNET can realize its goal of being the primary repository for food safety data. Any effort to improve food and feed-testing data exchange must address both the technical and policy issues.

Introduction

Foodborne illness outbreaks are increasingly national and international in scope. Despite a growing movement to “eat local,” packaging and transportation technologies have enabled the food industry to transport food long distances to reach intended consumers. The transportability of our food means that a contaminated product can reach consumers in sporadic locations across the country or internationally, which can complicate outbreak detection and investigation. Even for local incidents, an effective food safety surveillance and response system can protect the public from foodborne disease. Food safety systems by necessity involve diverse stakeholders, including agricultural, clinical, chemical, environmental and other laboratories; local and state health departments and departments of agriculture; state and federal epidemiologists; healthcare providers; outbreak investigators; food and feed-testing laboratories; federal agencies such as the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Centers for Disease Control and Protection (CDC); and field and contract laboratories that work with FDA and USDA. When dealing with a foodborne disease outbreak, a timely and coordinated response is critical. To plan this response, investigators need all available data as soon as possible. With so many stakeholders involved in the data collection and outbreak response processes, and with often limited IT resources, the data integration this entails can be challenging.

Decision-makers at the state and federal levels realize the importance of reliable, efficient data exchange to a coordinated response to foodborne disease outbreaks, and on January 4, 2011, Congress passed the Food Safety Modernization Act (FSMA), which establishes an integrated food safety system (IFSS) as a national goal and also calls for enhanced partnerships at the local, state and federal level. FSMA aims to help the nation’s food safety system prevent outbreaks, rather than simply respond to them. This aim requires new approaches to food safety, including increased data sharing capabilities. (FSMA, 2011) The present document presents a snapshot of current data exchange practices in the food safety system and describes some of the many initiatives that are working towards the goal of an IFSS (see Appendix F for a list of these initiatives). While in many ways a fully integrated food safety system is still an unrealized ideal, APHL is committed to working with FDA towards that goal.

Purpose of the Discovery Document

The cooperative agreement between APHL and FDA has charged APHL Informatics with establishing nationally accepted models for the rapid sharing and acceptance of laboratory data by FDA and partnering regulatory agencies in order that those agencies may pursue regulatory action and advance public and animal health. As a first step in this process, APHL has conducted a period of discovery regarding the current landscape of food and feed-testing laboratory data. As per the cooperative agreement, APHL’s research builds on the existing work of the Partnership for Food Protection (PFP) and concentrates on the reporting and use of the Electronic Laboratory Exchange Network (eLEXNET) database.

The present document is the result of this period of discovery. It summarizes APHL’s research, identifies gaps in the landscape and offers suggestions for next steps, based on this research. APHL is hopeful that the FDA will find this document useful in planning further steps for the cooperative

agreement with APHL and for developing future projects, either internal to FDA, or in collaboration with other local, state and federal partners.

Discovery Phase: Scope and Methodology

This section summarizes APHL's activities during the discovery phase and the strategies used to collect information on food and feed-testing data exchange. In addition, it describes the process of revision, review and approval that APHL followed to draft the discovery document.

Scope

The landscape of food safety is broad, involving multiple stakeholders; local, state and federal agencies; diverse laboratories; and many collaborative initiatives. In addition, many of these agencies utilize multiple data collection tools and varied reporting mechanisms. APHL discovered quickly that this discovery document cannot possibly be comprehensive to cover all food safety reporting and public health data exchanges and that it would be necessary to clearly define the scope of our discovery research. APHL determined that it could best fulfill its charge by focusing on the data flows between food and feed-testing laboratories at the state level and the FDA, particularly the data that state laboratories submit to the eLEXNET system. Specifically, APHL concentrated on the following components of the data exchange landscape.

- 1. Data Exchange Capabilities of State Laboratories.** In order to identify the gaps and opportunities that exist and therefore to provide recommendations for how to improve data exchange in this realm, it was critical to understand the current informatics and data exchange capabilities among food and feed-testing laboratories.
- 2. Reporting to FDA Currently.** What reporting requirements do food and feed-testing laboratories, including FERN participants, currently follow? How do laboratories satisfy these reporting requirements? How and to whom (and how often) do laboratories submit testing and results information? Do differences in reporting protocols of state and federal agencies place an onus on laboratories and IT staff or create redundant reporting requirements? Are reporting requirements clear and consistent across laboratories? When and how do laboratories submit data to eLEXNET? What reporting requirements do these submissions satisfy?
- 3. What do laboratories want?** What do laboratories need in terms of data exchange? What are the most common problems that laboratories have with data exchange as it currently exists?
- 4. What do end users need?** eLEXNET is intended to capture laboratory testing and results from food and feed-testing laboratories to use in surveillance. What are the needs of the end user of such data? How do state and federal agencies (want to) use these data for surveillance and outbreak response? Do current data interfaces satisfy all of these needs?

While APHL's primary focus was data exchange between state laboratories and FDA, the project team nevertheless attempted to capture efforts that are similar to, or that have an impact on, eLEXNET or on food safety data exchanges (see "Data Exchange Initiatives" below). By knowing about these

parallel efforts, FDA can choose to collaborate, where appropriate, with these other programs. Such collaboration may allow FDA to 1) participate in the development of methods and research; 2) benefit from the lessons learned from development and implementation of data exchanges; 3) reuse tools, software, and platforms developed; 4) build interoperability between eLEXNET and other systems under development.

Methodology

Interviews

During the discovery period, APHL engaged stakeholders in state laboratories and across FDA offices, as well as in other federal agencies, including USDA. APHL interviewed numerous individuals from these agencies with the aim of gathering a diverse set of opinions and ideas that would be representative of the community as a whole (see Appendix D for a list of all interviewees). APHL tailored its questions to the perspective of the interviewee, though APHL asked each subject about where they saw room for improvement. The interviews fall into three broad categories.

- 1. Laboratorians.** What are their reporting requirements? Does their laboratory submit data to eLEXNET? If so, how often? What would their ideal data exchange system look like?
- 2. eLEXNET contractors.** How is the system set up? How are changes made and new laboratories on-boarded? What are the plans for the future of the system?
- 3. Agency staff, including FDA and USDA staff involved in foodborne illness surveillance and response.** These are the main contributors and end users of the data collected in eLEXNET and in related databases. What do they need to facilitate their analyses?

The subject matter experts who APHL interviewed provided valuable insight into food safety data exchange and helped to identify the systems, data flows and documentation that fell within the scope of our project.

Survey

As part of the discovery process, APHL conducted a survey of the 31 food and feed-testing laboratories that have received FDA funding to pursue accreditation. This survey collected information regarding the laboratories' information systems and data exchange capabilities and their use of the eLEXNET system. The survey questions are attached to this report as Appendix E. APHL used the survey results, along with information obtained through interviews, to identify trends among food and feed-testing laboratories.

For the purposes of this discovery document, APHL limited the survey sample to these 31 laboratories in order to expedite the survey process. These laboratories have members serving on the Accreditation Workgroup who are already familiar with this cooperative agreement and with the APHL project team. APHL recommends expanding the sample to include other laboratories as part of the second-year activities. Laboratories that are in a position to seek accreditation may be in the forefront of the food and feed-testing laboratory community in terms of data and process management, and therefore their responses may not be representative of the community as a

whole. Nevertheless, it is clear from survey results that much work needs to be done for even these laboratories to exchange data interoperably with FDA.

Documentation

APHL also gathered documentation in the form of progress reports about specific initiatives or pilot projects, data exchange implementation manuals, online websites and databases and other resources (see Appendix C for a full bibliography). Resources consulted include:

- 1. eLEXNET documentation.** The eLEXNET staff provided informational material, including brochures, help files, upload templates and implementation guides.
- 2. FDA documentation.** APHL gathered a variety of FDA documentation, including progress reports, laboratory manuals, reporting requirements, presentations and project planning documents.
- 3. Reports by other agencies or collaborative teams and workgroups, such as the Partnership for Food Protection (PFP) and the Council to Improve Foodborne Outbreak Response (CIFOR).**

User Group

During the discovery phase, APHL relied heavily on the expertise of the National User Group, convened as a part of this cooperative agreement. The User Group was critical in helping to identify areas of interest for this report. The group also reviewed several drafts of this document to make sure it conveyed a clear and accurate description of the landscape and offered balanced, useful recommendations that would enhance data exchange between FDA and food and feed-testing laboratories. The members of this advisory body were drawn from state laboratories and represented APHL, AAFCO, and AFDO; several FDA liaisons also attended meetings. Most members of the group have been users of the eLEXNET system at one point or another, and so contributed valuable insights into how to enhance the system's interface with laboratories and outbreak investigators. The initial User Group meeting was held on July 9. The purpose of this 'Kickoff Meeting' was to introduce the members of the group and to discuss the short and long term goals of the group. For a list of the members of the User Group, see Appendix B.

The User Group offered feedback on the discovery document during two formal review periods. First, each member of the group was encouraged to review the initial draft and to return a feedback form to the project team with comments, edits, and questions. The project team incorporated the suggestions and revisions offered by the User Group and then forwarded the subsequent draft to the User Group for a second review, during which the User Group recommended further revisions to the document. On July 25, the User Group conducted a three-hour conference call to carefully review each section of the document. Once the project team incorporated the suggestions made at this meeting, the User Group completed its review of the document on August 9, 2013.

Final Document

Methodologically, the discovery document combines the information obtained from written sources,

oral interviews and the expertise of the User Group. The final document summarizes the current data exchange landscape, in particular the data flows that exist between state laboratories and FDA. Where appropriate, the document also touches on the connections between agency systems (both inter-agency and within FDA). In the final section, the document delineates specific strategies that FDA may consider pursuing to augment this landscape.

Data Exchange Initiatives

While FSMA encouraged collaborations between local, state, and federal agencies, including the partnership of FDA, APHL, AAFCO, and AFDO in the current initiative, the Act was itself a product of the community's commitment to creating an IFSS by leveraging information technologies. The landscape of public health data exchange, including the exchange of food safety data, is changing rapidly, motivated by a desire to leverage new technologies to enhance surveillance and operational systems. While the primary activity of this discovery phase is to document the data exchange between the food and feed-testing laboratories and eLEXNET, it is important to recognize that there are several existing food safety-related data exchange processes in place or in development. The efforts to ensure the safety of the food consumed in the United States are carried out by many different organizations; these collaborations are summarized in Appendix F, and those that have a significant bearing on the current project are discussed below.

FDA Initiatives

This section describes initiatives primarily sponsored by FDA.

Field Accomplishments and Compliance Tracking Systems (FACTS)

FDA uses FACTS to track inspection data. States that perform contract inspections for FDA enter data into FACTS via a web portal, the Electronic State Access to FACTS (eSAF). eSAF is the only external system FDA maintains to exchange inspection info with regulatory partners. About 10,000 state inspections have been recorded in the system since its inception. (FDA, "Q&A: Food Protection Plan," 2013) Selected data from FACTS are transferred to eLEXNET on a daily basis; this transfer accounts for approximately 65% of the data in eLEXNET.

Mission Accomplishment and Regulatory Compliance Services (MARCS)

MARCS consists of diverse applications and services that streamline the business processes of FDA's Office of Regulatory Affairs (ORA) and provide better access to information. These software applications and services are being implemented on shared technology platforms. The goal of MARCS is to establish the full and complete integration of FDA ORA internal systems, including district offices and laboratories. (SRA, 2012)

The MARCS project efforts have been slowed due to fiscal and resource constraints. While FDA acknowledges the value of the concept behind MARCS, the funding necessary to execute the concept is difficult to obtain. The MARCS team is focused on small, exploratory steps to prove the concept and build momentum for the rest of the effort.

Food Emergency Response Network (FERN)

Organized by FDA and USDA's Food Safety and Inspection Service (FSIS), FERN is a collaboration of more than 170 laboratories that integrates multi-level food-testing laboratories to detect and respond to public health emergencies, including acts of bioterrorism, involving the food supply. FERN also plays an active role in the Integrated Consortium of Laboratory Networks (ICLN), which establishes a framework for coordinated, integrated responses by multiple laboratory networks

(including FERN, CDC's Laboratory Response Network [LRN], EPA's Environmental Response Laboratory Network [ERLN], USDA's National Animal Health Laboratory Network [NAHLN] and others) to major multi-jurisdictional incidents (ICLN, 2012). FERN utilizes state laboratory data in the context of a national work plan. (Sciacchitano, Undated) FERN participants upload results for proficiency tests to eLEXNET. Test results for specimens involved in a FERN event are also transferred to eLEXNET as part of a laboratory's normal upload process.

Partnership for Food Protection (PFP)

The PFP is a multi-agency initiative that was established following the 2008 50-State Workshop, a biannual event that brings together participants from all disciplines of food safety and public health. The PFP is composed of federal, state and local government officials dedicated to building the foundation of an IFSS.

The PFP consists of several focused workgroups that are assembled and dissolved as specific tasks are completed and the scope of the PFP's mission evolves. The labors of each workgroup promote the development of an IFSS and contribute to the goals outlined in FSMA. The findings of the Integrated Information Technology Workgroup and the Laboratory Workgroup are of particular interest for data exchange, though it should be noted that the Laboratory Workgroup disbanded in 2013.

The goal of the Laboratory Workgroup was to develop national standards to produce consistent and meaningful analytical results. To this end, the workgroup's seven subcommittees worked on a number of projects. The Standardized Worksheets Subcommittee was devoted to developing uniform standards for recording raw analytical food-testing data and developed a worksheet to facilitate this recording. The Reporting Subcommittee was charged with developing national standards for reporting analytical data and making recommendations for future development of electronic data capture; it also created a catalog of IT systems commonly receiving laboratory data. The primary work product of the Laboratory Workgroup is the "National Standards for Food/Feed Testing Laboratories: A Guidance Document for Food/Feed Testing Laboratories Performing Analysis in Support of Regulatory Action." This document is being reviewed by FDA and has not been published.

The charge of the Integrated Information Technology Workgroup (IIT WG) is to define and understand the requirements for developing an integrated electronic information management backbone, and undertake technical projects to create an interoperable and integrated national food safety system. The IIT WG has focused on information systems which support business processes outside the laboratory. Current projects include developing a data dictionary of standard terminology and establishing a plan to increase the number of agencies capturing a minimum set of these common data elements for investigations, recalls and inspections. In addition, the IT WG has already successfully piloted a one-way data flow of inspection data from the Pennsylvania Department of Agriculture to FDA's eSAF system. The Department of Agriculture now seamlessly transmits BSE inspection data from its system to FDA's eSAF. FDA then moves the data from eSAF to FACTS. (PFP, 2013)

External Initiatives

This section discusses initiatives that have been sponsored primarily by agencies other than FDA.

Council to Improve Foodborne Outbreak Response (CIFOR)

CIFOR is sponsoring a number of projects with the goal of improving foodborne outbreak response. Through CIFOR's Epi/Lab Integrated Reporting project, APHL is piloting one model site and three pilot sites to develop combined epidemiological and laboratory reports in a standard format that will eventually allow reporting between jurisdictions. For this project, CIFOR developed an open-source application that combines multiple laboratory data into a single report. To date, three states have successfully piloted the application; the next phase will include epidemiological data. (APHL, 2013) For more information about this project, visit <http://www.aphl.org/aphlprograms/food/initiatives/Pages/epilab.aspx>.

Centers for Disease Control and Prevention (CDC)

CDC has partnered with APHL and other agencies on a number of data exchange initiatives, including the Public Health Laboratory Interoperability Project (PHLIP), the Vaccine-Preventable Diseases Project and the Laboratory Response Network (LRN). These projects provide technical support to public health laboratories (PHLs) to implement electronic data flows to CDC. Most PHLs involved in these projects send Health Level 7 (HL7) messages via the Public Health Information Network Messaging System (PHIN MS) to the APHL route-not-read (RnR) Hub, where the message is redirected to CDC's data and message brokering section. The Hub alleviates the burden of point-to-point contacts that the laboratory must maintain.

The LRN is a national network of more than 150 laboratories in federal, military, state and local health organizations. It is tasked with maintaining a national capability to respond to biological and chemical threats and other public health emergencies. The LRN provides a staged approach to data exchange. For participating laboratories that are not ready to design an HL7 messaging solution, CDC has developed LRN Results Messenger, an application that allows the laboratories to immediately fulfill the data exchange needs of the LRN. This software solution shifts the balance of resources needed (e.g., software developers, IT staff, etc.) to CDC and enables the exchange of tightly controlled messages with relatively low maintenance. Laboratories that have the ability to exchange HL7 messages directly from a LIMS may elect to automate LRN reporting as part of the LRN Laboratory Information Management System Integration (LIMSi) project. The advantages of the LIMSi approach include the elimination of double data entry, the ability to manage LRN data within the laboratory's familiar workflow and systems, the increased availability of LRN testing data for local disease surveillance and the implementation of common data standards and messaging infrastructure that can be utilized by the laboratory for other reporting needs.

Notably, both LRN and PHLIP have started working with LIMS vendors to provide modules with the LIMS package that will generate an appropriately formatted message. These modules reduce the level of effort involved in producing the message for these data flows. (APHL, Undated; CDC, "Laboratory Response Network," 2013) For more information, visit <http://www.bt.cdc.gov/lrn>.

CDC, in partnership with Palantir Technologies, has recently developed two food-safety surveillance systems that integrate datasets from diverse sources. The Foodborne Disease Outbreak Investigation System (FDOIS) combines data from, among other sources, PulseNet and the National Outbreak Reporting System (NORS). The second, the System for Enteric Disease Response, Investigation, and Coordination (SEDRIC), integrates epidemiological, laboratory and traceback data from a variety of sources. Partners enter data into the systems through a web browser. It should also be noted that FDA plans to work with Palantir to develop a disease investigation and response infrastructure. (Palantir, Undated; Williams, 2013)

Environmental Protection Agency (EPA)

In 2008, EPA established the Environmental Response Laboratory Network (ERLN), which functions much like FERN. Member laboratories across the US operate as a network to provide analytical support during a large scale environmental event. ERLN requires that member laboratories establish a documented laboratory quality system and participate in EPA-managed external quality programs which monitor the laboratory procedures used and the data generated by each member laboratory. One component of these programs is the WebEDR service (<http://webedr.fedcsc.com/app>), a web-based application configured with approved ERLN analytical methods and their associated measurable quality objectives (MQO). When a member laboratory uploads the raw data for an analytical run for a specific method, WebEDR compares the laboratory data to the method's MQOs and notifies the user of the validity of the run.

Laboratories can submit data to ERLN using three different methods, each of which is designed to support different emergency scenarios. For time-critical decisions, data uploads consist of a limited number of required data elements and are formatted as spreadsheets or CSV files. Users can submit more extensive reports in XML format with a variety of additional data fields and measurement quality parameters. The most detailed report provides sufficient information for the user to recreate the analytical run as it was performed in the laboratory.

EPA has applied some of the lessons learned working with ERLN data standards in other areas. For example, EPA has developed several data exchange formats (e.g., eDWR, SDWIS, AQDE, AQS-Air, ICIS-NPDES-Water, NetDMR, OWIR, ODPX, WQDE, WQX, HERE and SRS) which are specific to the types of specimens or methods used. Visit www.exchangenetwork.net for more information on many of these formats. (Exchange Network, 2013)

In 2012, EPA and APHL published a white paper that describes an environmental electronic data deliverable (EDD) with a standardized, defined list of data elements and their associated data structures and components. The proposed EDD is based on the tiered data submission formats that EPA developed for ERLN. The minimum data set in the EDD would be appropriate for reporting to local, state and federal agencies. The adoption of EDDs would enhance interoperability of systems and reduce duplicative reporting. (APHL, 2012)

In addition to these guidance documents, EPA has developed software tools that assist directly in managing environmental data. Scribe, developed by EPA's Environmental Response Team (ERT) parallels the LRN Results Messenger in terms of functionality. Users in the field can import EDD-formatted data, including sampling, observational, and monitoring data, into Scribe, and end-users

can manage, query, view, export, and report the data. (EPA, Undated)

USDA Food Safety and Inspection Service (FSIS)

In 2010, the USDA FSIS announced its intention to launch the Public Health Information System (PHIS) as a comprehensive, web-based, data analytic system. Once implemented, PHIS will replace several legacy systems and integrate FSIS data streams. FSIS will use PHIS to receive and analyze data from food safety agencies across the country, issue export and import certificates, and facilitate international cooperation in food safety activities, including system-to-system communications and data exchange. Earlier this year USDA started the rollout of PHIS to FSIS-inspected domestic food production establishments and official import inspection establishments. (USDA, FSIS, 2010) For more information, visit <http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/phs>.

Assessments

Several efforts have been made to assess the current state of informatics capabilities among public health agencies and laboratories. Some of these efforts have also attempted to identify gaps and articulate the informatics needs of public health surveillance and emergency response on the local, state, and federal level. This knowledge is essential in planning initiatives that will further the goal of an IFSS. Below is a summary of some of these evaluative efforts. These assessments and their findings informed the approach taken during this discovery phase.

Laboratory Efficiencies Initiative Self-Assessment Tool

In June 2013, the Laboratory Efficiencies Initiative (LEI), a collaborative effort between APHL, CDC and PHLs, released a Self-Assessment Tool that allows PHLs to assess their overall informatics capabilities in 19 specific areas. Data exchange and interoperability are key themes in the assessment. In the coming months, APHL plans to collect responses to the assessment in order to establish a national baseline of informatics capabilities. (APHL & CDC, 2013) Importantly, the tool is flexible enough to allow a PHL to take an all-encompassing enterprise approach when completing the assessment, or to assess individual programs (e.g., FERN). To access the self-assessment tool, visit <http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Pages/Informatics.aspx>.

National Opinion Research Center (NORC) at the University of Chicago

In a project funded by the Assistant Secretary for Planning and Evaluation at the United States Department of Health and Human Services, NORC assessed trends in the use of information technology by public health departments at the state and local level. Notably, NORC's report includes a catalog of national informatics organizations, including the Public Health Data Standards Consortium (PHDSC), the Public Health Informatics Institute (PHII), and others. NORC's report did not assess data exchange between state and federal agencies, or from laboratories to state health departments or federal agencies. Nevertheless, many of NORC's observations and recommendations apply to laboratory settings as well. For example, NORC highlighted the need for sustained and flexible resources, workforce training, business process analysis and the use of standards and interoperable systems. Currently, public health relies on non-integrated IT systems, which results in the creation of insulated silos that cannot share data. NORC observed that state and local health

departments would benefit from technical assistance programs that offer support with workflow optimization, data standards, and other informatics and IT challenges. In addition, NORC reported that agencies could use assistance selecting vendors, describing requirements and configuring new applications. (NORC, 2013) Such a program would also benefit food and feed-testing laboratories.

Partnership for Food Protection

The PFP compared the functionalities of seven databases that collect food safety data, such as inspection and recall data and laboratory results. The databases reviewed included eLEXNET, FDA's eSAF, FDA's Reportable Food Registry (RFR), FDA's Recall Enterprise System (RES), CDC's PulseNet, the North Carolina Recall System, and FoodSHIELD. The PFP assessed the databases' ability to import and analyze data and the accessibility of the user interface. The PFP survey did not examine the capabilities of laboratories contributing data to these systems. (PFP IIT WG, 2010) The PFP's pertinent observations about eLEXNET are discussed in the State Laboratory Capabilities and FDA's eLEXNET section below.

Yardstick Self Assessment Tool for Public Health Food Safety Testing

A joint task force convened by APHL, in collaboration with CIFOR, has developed the Yardstick Self Assessment Tool for food safety laboratories. Laboratories can use the tool to assess their overall capabilities with regard to testing procedures, reporting, data management, administration and other areas of administration. Several questions in the Yardstick pertain to electronic data exchange capabilities and data sharing with eLEXNET. APHL published the Yardstick on its website in 2012 (APHL Yardstick Task Force, 2012). The survey is intended primarily for internal use by laboratories, and, to date, neither APHL nor CIFOR has collected results data.

High-Level Findings and Recommendations

During this discovery period, APHL found many instances of high-level officials calling for improved surveillance and a more integrated food safety system. Indeed, the present project is not the first time that FDA has sought guidance on informatics issues from a specially-formed workgroup or task force. Since 2008, the PFP has been working on initiatives that promote the development of an IFSS and has presented annual reports and recommendations at the 50-State Workshop. Furthermore, in September, 2011, FDA Commissioner Margaret Hamburg formed the IFSS Task Force (ITF) to find ways FDA can improve its business processes, especially with regard to integration. The PFP and the ITF are made up of FDA senior staff and state representatives. APHL would be remiss in its discovery process if it did not review the findings and recommendations that these groups have made. Moreover, APHL's findings are in consensus with many of the observations of the IFT and the PFP.

IFSS Task Force (ITF)

On December 21, 2010, when Congress passed the Food Safety Modernization Act (FSMA), Commissioner Hamburg asserted that, "[The Act] has laid the critical foundation for a **prevention-based** 21st-Century food safety system." (Hamburg, 2010) To continue building this foundation, Commissioner Hamburg assembled the ITF in 2011 to develop and implement partnerships between federal, state and local agencies.

The ITF offered numerous recommendations at the 2012 50-State Workshop in Denver, Colorado, on how to achieve an integrated, prevention-based food-safety system. In its presentation to the Workshop, the ITF noted that information technology needs are critical to the utilization and integration of laboratory data, and addressing these needs will require a long term strategy with prioritization of efforts. Of the recommendations the ITF made, the most relevant to this report is the need for FDA to develop internal and external clarity around the primary public health mission and operational activities within the Foods Program. On a more granular level, the ITF recommended that FDA work to improve the timeliness and consistency of how information is shared between FDA and states by pursuing information sharing agreements with states. The ITF also recommended identifying IFSS best practices and improving the consistency and implementation of these practices across the federal-state system.

Partnership for Food Protection

In March 2012, the PFP observed that, “As part of the FDA Food Safety Modernization Act (FSMA), signed by President Obama on January 4th, 2011, FDA’s approach to food-borne illness is shifting from post-outbreak reaction, to **early detection and prevention** of contamination.” (PFP, 2012) In its report to the 50-State Workshop two years previously, the PFP IIT WG identified seven challenges to the global integrated IT system that would facilitate this prevention-based approach. These challenges include 1) heterogeneous systems; 2) unifying data structure; 3) standardized structural metadata; 4) information ownership; 5) system operations and maintenance; 6) information privacy and security; 7) mutual and individual benefits. (PFP IIT WG, 2010)

The IIT WG made several recommendations to address these challenges.

- Identify why more people are not using existing systems and enable more people to use them.
- Continue to identify existing systems that are collecting food safety and regulatory-based information and understand how these systems meet the needs of current users and could meet the needs of a larger audience.
- Encourage owners of existing systems to continue to make enhancements along the lines of data exchange and interoperability.
- Encourage the development of a system (or systems) that captures establishment and inspection history data that can be pre-populated and used remotely in the field.
- Some states/locals/others have built systems on a smaller scale that are meeting an identified need. Provide a cooperative agreement /grant process to pilot these systems on a national scale.
- Work towards interoperability of existing and newly-developed systems. Several state and local agencies have or are considering development of internal systems for inspections and other information. A mechanism that would allow these systems to share information (rather than converting to a new system) is highly desired. (PFP IIT WG, 2010)

The ITF and the PFP reflect the opinions of leadership in the food safety system. Therefore, they

provide insight into the vision that this leadership has for a prevention-based IFSS. Both workgroups emphasized the need for consistent data sharing processes across agencies. Furthermore, the PFP and the FDA Commissioner both noted FDA's commitment to a shift to a prevention-based food safety system. This shift in approach marks an important change in policy. As APHL reviewed the landscape of food safety data exchange, we considered to what extent the eLEXNET system and the existing data exchange mechanisms between FDA and state laboratories meet the stated objectives of the ITF and the PFP.

Chapter Summary

This brief review of data exchange initiatives reveals several trends. First, the public health community recognizes the critical role that data exchange plays in an IFSS. Second, most of the data exchanges described, including ERLN, FERN and LRN, are purpose-built to meet a specific need. Interoperation with other systems was not a goal when these systems were initially built. Third, many of the initiatives described do not support electronic exchange, and, for those that do, often laboratories are not utilizing that functionality. Notably, some initiatives (e.g., LRN and ERLN) have adopted a staged approach to data exchange, allowing the message structure or the transport method to change, depending on the time-sensitivity of the information or the IT capabilities of the laboratory. Nevertheless, systems such as FERN, FACTS/eSAF and PHIS still largely depend on paper-based systems with test results being manually entered into centralized database systems. When electronic transfer is being used, very few existing data exchange standards are applied across multiple disciplines. Replacement systems such as MARCS and PHIS are being developed. However, there is much work remaining before these systems are fully developed and implemented. Validation of testing results is a critical factor in data exchange between agencies. The methods used and the acceptance criteria applied in data validation may also compromise the ability of laboratories in different programs to share data. It is not clear that interoperability across agencies is a design goal for these systems at this point.

The brief survey performed during this discovery period is the only survey of which APHL is aware that polled respondents about data exchange capabilities in food and feed-testing laboratories. Past assessments have attempted to measure the informatics capabilities in food inspection and safety agencies (NORC, 2013); management, business process and testing capabilities in food-testing laboratories (APHL Yardstick Task Force, 2012); data exchange capabilities of national food database (PFP IIT WG, 2010) and informatics capabilities in public health laboratories generally (APHL & CDC, 2013). Therefore, the discovery phase has identified an important gap in our knowledge of the laboratory data exchange landscape, a gap that the initial efforts of this project have begun to fill in. It is critical to have a thorough understanding of the data exchange mechanisms that laboratories can currently perform. This knowledge will influence decisions about the best use of resources and the direction and scope of enhancement efforts.

State Laboratories and FDA's eLEXNET

This section summarizes the informatics and data exchange capabilities of food and feed-testing laboratories and highlights gaps in these capabilities. It also presents an overview of the eLEXNET system, the system's data exchange mechanisms and current trends among the system's users. It identifies components of the state-to-FDA data exchange system that may need improvement.

Laboratory Informatics Capabilities

APHL's discovery phase revealed that the testing volume, data exchange capabilities and informatics needs of food and feed-testing laboratories vary widely from state to state. The number and types of products tested by individual state laboratories depend largely on the mission of the laboratory in that state. Some laboratories test a small number of specific food and/or feed products. When additional types of tests are needed, the laboratory may establish a memorandum of understanding (MOU) with another state or federal facility to perform the testing. Other states have comprehensive laboratories with little need for testing by external laboratories. State food and feed-testing laboratories also collaborate with other laboratories to cross-train their personnel to provide additional testing capacity during emergencies. Within the laboratory, sample tracking is typically accomplished by using electronic systems, whether spreadsheets, databases or laboratory information management systems (LIMS). These systems often determine the data formats and exchange protocols that the laboratory utilizes.

Given the diversity of laboratory informatics needs, data exchange capabilities, and information management systems, it is unlikely that a single data exchange solution will work efficiently for every laboratory.

Laboratory Information Management Systems (LIMS)

The tracking tools that laboratories use vary widely. Many smaller laboratories with lower data volume use custom-configured MS Access databases or Excel spreadsheets to store and report test results. These systems are capable of automated data exchange but frequently lack important functionality such as audit trails and multi-level data security. Conversely, some laboratories have a large staff and perform thousands of tests per year. These laboratories may implement highly automated systems with sophisticated LIMS to handle a significant percentage of the routine data-handling chores. These systems are fully capable of data exchange with other systems in multiple step processes of automated data extraction, encryption of results, and information transfer.

A LIMS is a significant investment for a laboratory. In addition to the initial purchase price, the laboratory must consider the cost of implementation, as well as continuing maintenance and service costs. Whether this investment is justifiable for the laboratory depends on a number of factors, including testing volume and size of the laboratory. For example, one Quality Manager at a facility that tests approximately 100 samples per month reported that her laboratory had rejected a LIMS as economically unfeasible and logistically unnecessary.

Table 1: LIMS Used in Surveyed Laboratories

LIMS in use in at least one area of the laboratory	Number of laboratories
Accelerated Technology Services Sample Master	3
BEAST	1
Cerner Millennium	1
Chemware Horizon	1
Ethosoft X-LIMS	1
Harvest	1
Homegrown	5
LabLynx eLAB	1
LabVantage Sapphire	1
LabWare	1
LITS Plus	1
NW Analytical	1
OpenELIS	1
PerkinElmer LabWorks	2
PerkinElmer Specimen Gate	1
Promium Element	2
Psyche Systems LabWeb & Outreach	1
Reflection X	1
StarLIMS	5
SUNRISE	1
Thermo Fisher Scientific Nautilus LIMS	1
USA Plants	1
USALIMS	1

Of the laboratories surveyed during this discovery period, about 86% (25 out of 29) use a LIMS. As Table 1 demonstrates, food and feed-testing laboratories have chosen to implement a wide variety of LIMS. At 19% each, StarLIMS and home-grown systems were the most common LIMS options. These results are similar to a 2007 survey of environmental laboratories in which APHL observed that 84% of laboratories use a LIMS. According to this 2007 survey, environmental laboratories use a wide selection of LIMS with no majority preference among different vendors; about 33% of these laboratories reported using a system developed in house. (APHL, 2007)

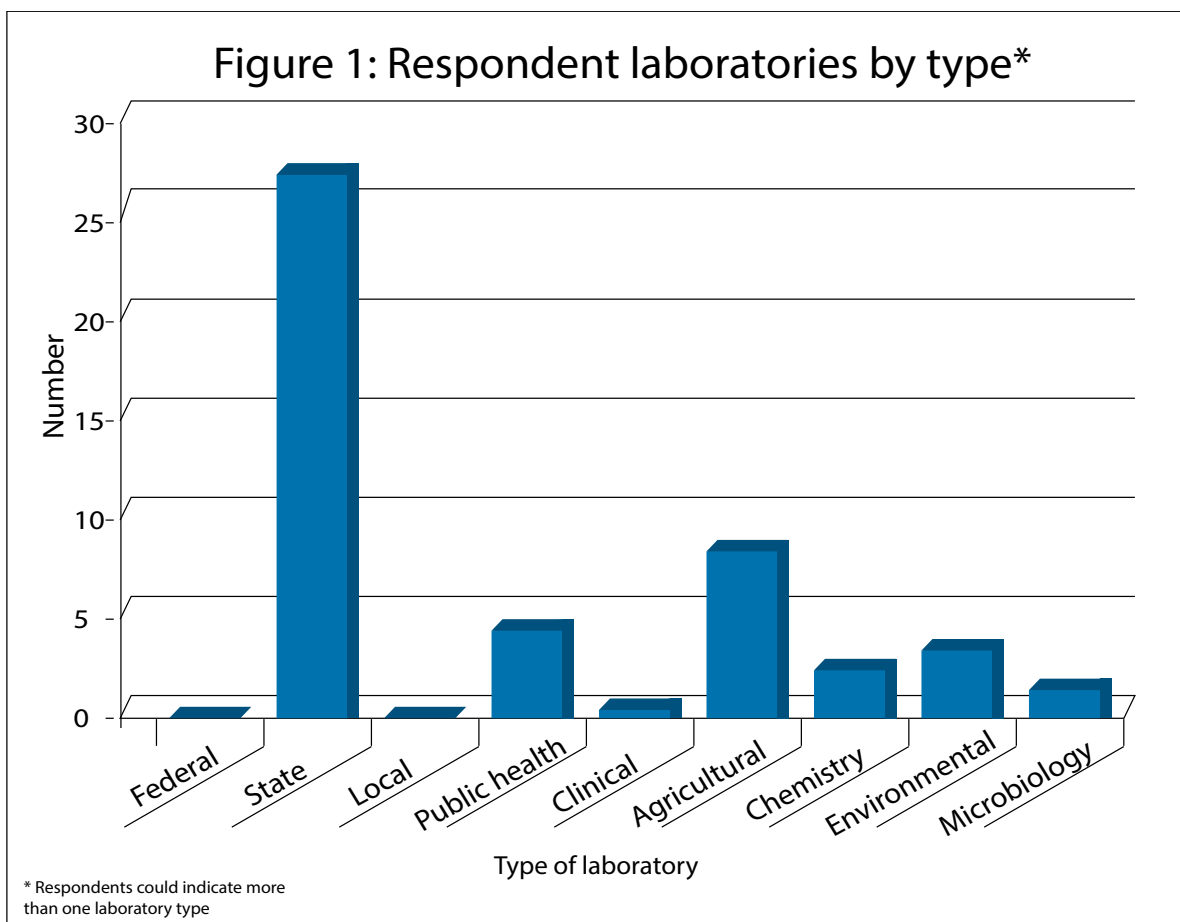
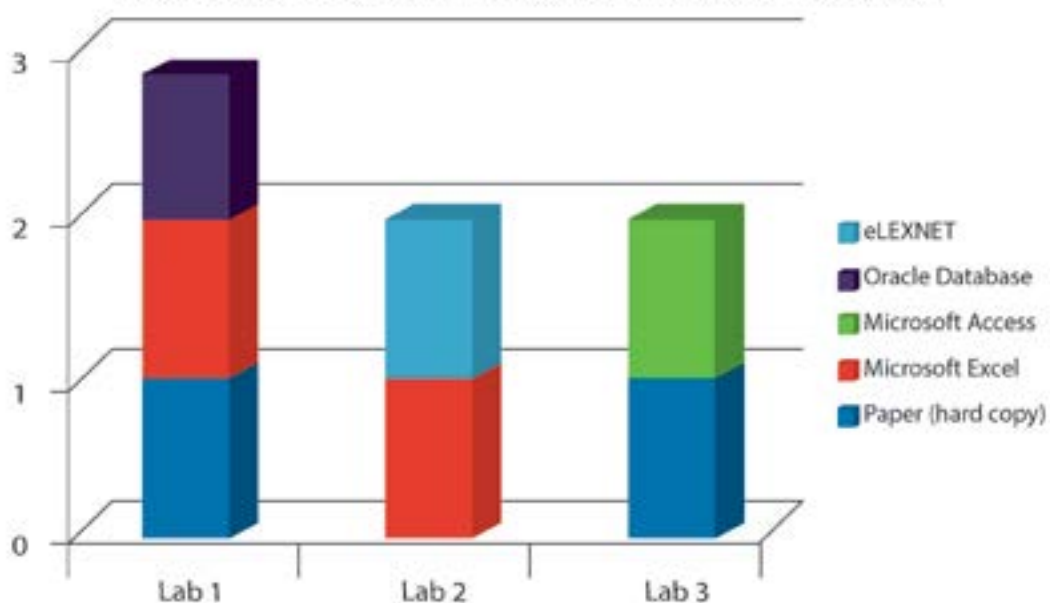


Figure 2: Systems used to manage and record laboratory tests and results in laboratories with no LIMS



One possible explanation for this diversity is that LIMS are often packaged and sold by laboratory type (e.g., agricultural, chemical, clinical, environmental, etc.), and food samples can be tested in a number of different laboratories. For example, survey respondents identified their laboratories overwhelmingly as “state laboratories,” but also as public health, clinical, agricultural, chemistry, environmental and microbiology laboratories (see Figure 1). Moreover, within the same laboratory, it is not uncommon for each functional area to install a different LIMS. Survey respondents were encouraged to note all of the LIMS in use in their laboratory. One respondent indicated that the laboratory had at least three LIMS deployed in the various functional areas of the laboratory: Promium Element for environmental samples, Cerner Millennium for clinical samples, and BEAST for forensic samples. In one case, the two installed LIMS fulfill different operational functions: Promium Element tracks testing data, and StarLIMS tracks laboratory certifications.

Of the laboratories not using a LIMS, 2 reported using paper-based systems, 2 Microsoft Access, 1 Microsoft Excel, and 1 an Oracle database (see Figure 2). Multiple answers were permitted for this question.

Many food and feed-testing laboratories are in the process of evaluating, purchasing and implementing LIMS. For example, a business analyst reported that her laboratory recently implemented X-LIMS, an Ethosoft product. Prior to implementation, laboratorians transferred data from paper forms into one of two electronic systems: on the dairy side of lab, a spreadsheet, and on the food side, an Access database. Another laboratory that APHL interviewed is in the process of converting from an Access database to PerkinElmer LabWorks.

Laboratories considering a LIMS can draw on a number of resources. In 2003, APHL, in collaboration with PHIL, published a guidance document that details the processes and workflows that a LIMS could logically provide. The entire guide is available on APHL's website (<http://www.aphl.org/aphlprograms/informatics/Pages/requirementslims.aspx>). (APHL, 2003) More recently, APHL's Informatics and Environmental Health departments published a white paper that describes consensus requirements for LIMS to automate production of standardized reports. The stated intent of this collaboration is to increase the percentage of laboratories that have interoperable LIMS that are integrated with the broader public health network. (APHL, 2010) Similarly, ASTM International, formerly known as the American Society for Testing and Materials, developed a Standard Guide for Laboratory Information Management Systems (LIMS) to educate general audiences in laboratories and other organizations that use LIMS. Like APHL's requirements, the guide establishes a minimum set of requirements for primary LIMS functions and provides guidance for all types of laboratories that are evaluating, purchasing, and implementing a LIMS. The ASTM Guide (ASTM E1578-06) is available for purchase on the ASTM website (<http://www.astm.org/Standards/E1578.htm>). ASTM has plans to update the guide and convened a workgroup for this purpose in 2012. (ASTM, 2012) Laboratories can use the APHL and ASTM guides to customize a Request for Proposals and articulate their needs to LIMS vendors.

It should be noted that these guides advocate configurable systems that meet reporting needs of clients without expensive customization for implementation. (ASTM, 2012; APHL, 2010; APHL, 2003) In response to this model, many LIMS vendors have been working with laboratory report recipients (including eLEXNET) to develop optional modules for the LIMS to automatically generate reports

formatted to the recipient's specifications.

In addition to a LIMS, some laboratories use an integration engine to perform such functions as validating, filtering, and mapping data, converting local codes to standard codes, and generating valid message structures. One systems architect with whom we spoke reported generating all of the laboratory's HL7 messages using an integration engine (Rhapsody); the laboratory had plans to add another integration engine (Biztalk) as well. This Texas PHL performs some (though not all) of the food testing for the state, and is interested in using Rhapsody to generate HL7 messages for eLEXNET. Of the laboratories surveyed during the discovery phase, seven use an integration engine (i.e., Rhapsody), 18 do not, and four did not respond to the question.

Current Data Exchange Processes

With a patchwork of regulatory and reporting requirements at the local, state, and federal level, laboratories face the challenge of reporting results to multiple jurisdictions. Eighty percent of the laboratories surveyed report results to three or more agencies or programs (see Figure 5). Four laboratories report to all eight of the agencies or programs mentioned in the survey, including:

1. State PHA or Department of Agriculture
2. Local PHA or Department of Agriculture
3. State PHL
4. CDC
5. FDA
6. USDA
7. EPA
8. FERN

With different reporting protocols, acceptance criteria, required data elements, and message formats for each agency or program, these obligations translate into a significant burden for the laboratory.

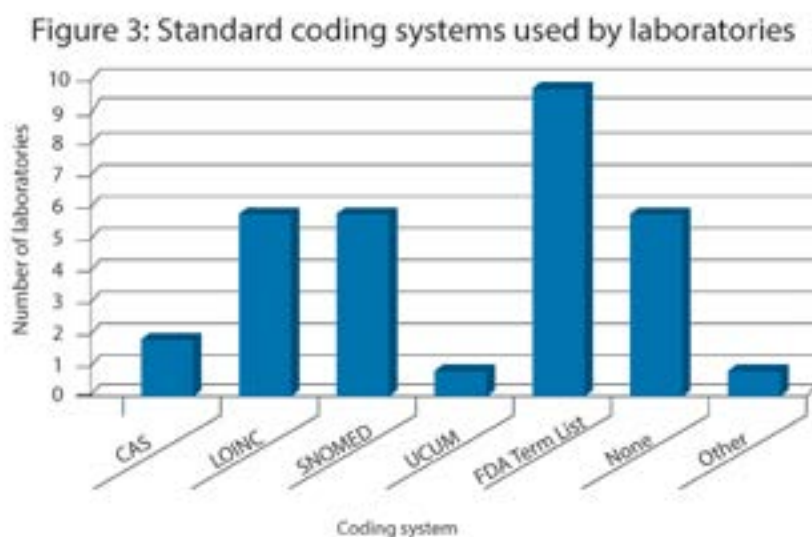
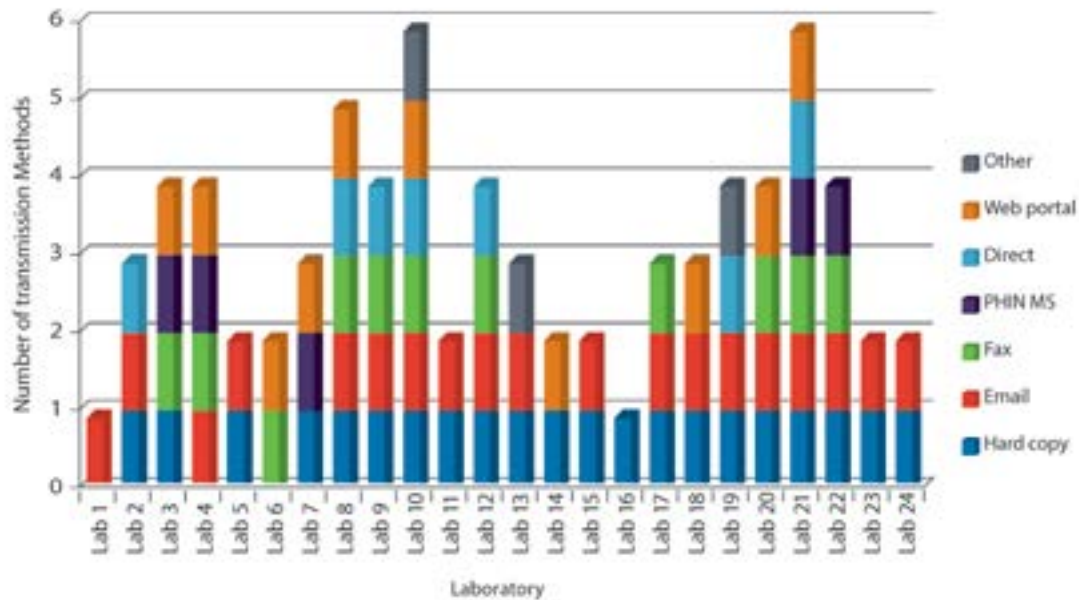


Figure 4: Methods of transmission used by each laboratory to report data to various recipients



Cumulative Methods of Transmission

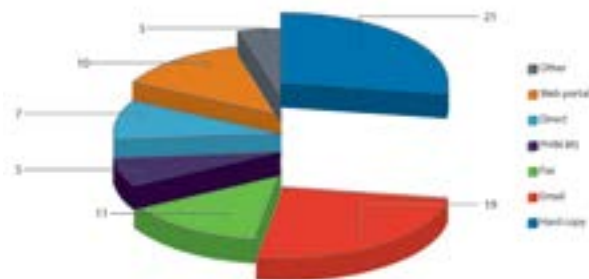
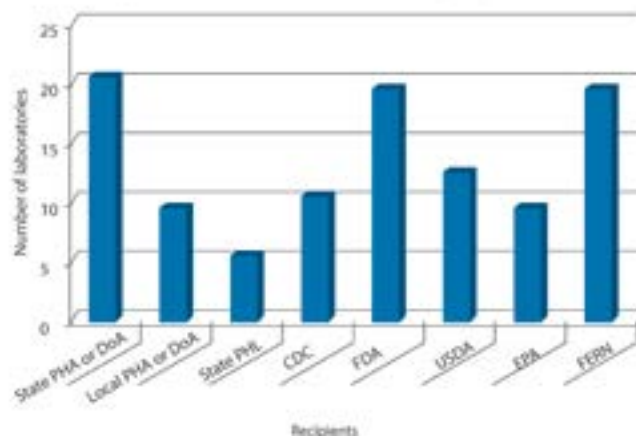


Figure 5: Recipients of laboratory reports



The majority of responding laboratories (88%) fulfill at least some of these reporting requirements with hard copy reports (see Figure 4). About 79% of laboratories send results via email. Forty-six percent send results by fax and 42% percent enter results into a web portal. Twenty-nine percent of responding laboratories use Direct and 21% use PHIN MS. Most laboratories (92%) use at least two methods of transmission to report results.

In terms of capabilities, seven of the surveyed laboratories can send and receive electronic messages for test results using agreed-upon standards and vocabulary for message creation and transmission. Another seven can send but not receive, and 11 reported no messaging capabilities. Of the 10 that can send electronic messages, eight can send CSV files, eight XML files, and eight HL7 messages, though only three laboratories reported the ability to send messages in all three formats.

The survey revealed limited adoption of vocabulary standards such as Chemical Abstracts Service (CAS), Logical Observation Identifiers Names and Codes (LOINC®), or Systematized Nomenclature of Medicine—Clinical Terms SNOMED-CT (see Figure 3). Seven laboratories use LOINC and SNOMED (no laboratory reported using just one of these standards). Only two laboratories reported using CAS, and both of these laboratories also use LOINC and SNOMED. Ten laboratories use the FDA Official Term List. Six laboratories indicated that they do not use any kind of standardized vocabulary apart from internal local codes.

The results of APHL's 2007 survey of environmental laboratories observed a similar finding: 70% of laboratories have not adopted nationally recognized electronic data standards. (APHL, 2007) The coding of testing methods and results is done on a per-laboratory basis. Without consistent coding of laboratory methods and testing results, the comparison of information across multiple laboratories without time-consuming recoding of the data is difficult or in some cases impossible. This lack of consistency in the data compounds the problem of retrieving and reporting of data across multiple jurisdictions. It is unclear at this juncture which, if any, of the existing standards, would be appropriate to implement in the food and feed-testing laboratory environment.

In its survey of food safety organizations, the PFP IIT WG observed a strong interest in expanding data sharing between the state agencies and federal agencies. While local agencies provide state organizations with mandated information and did not indicate a need for access to state or federal data, state agencies expressed a desire for better access to federal agency information, and federal agencies for local and state agency information. The majority of all respondents wanted improved search and reporting capabilities. (PFP IIT WG, 2010) This data sharing can facilitate foodborne outbreak investigations at the state and federal level, and is a prerequisite for an IFSS.

It should be noted that adoption rates among public health agencies (PHAs) are much higher than those observed for food and feed-testing laboratories in the present survey. Mandatory reporting requirements for infectious and communicable diseases, along with significant funding increases following the 2001 anthrax event, have driven the adoption of electronic data exchange by state PHAs. According to the Association of State and Territorial Health Officials' (ASTHO) 2011 Profile of State Public Health (Volume Two), 96% of states collect data related to communicable/infectious diseases and reportable diseases; 92% of these organizations track food-borne illness. For population-based activities, the majority of state health agencies indicate that they have automated electronic systems for communicable disease reporting (90%) and syndromic surveillance (>80%). Nearly all (96%) laboratories still enter data directly to one system or another, but 87% also perform batch file exchange using HL7. (ASTHO, 2011)

Preparing Laboratories for Data Exchange

It is important that a data exchange strategy address the significant diversity in the technical and systems capabilities of the laboratories submitting data to FDA. Many of the laboratories utilize manual processes or simple technical systems (e.g., Excel or Access) to manage data. These systems are simply not capable of sophisticated, standardized secure messaging such as HL7. While the technology utilized in these laboratories may be appropriate to the laboratory's needs, this situation nevertheless limits the mechanisms that the laboratory can leverage for data exchange. While laboratories with mature informatics capabilities and a sufficient volume of tests may choose to automate reporting, it may be possible for low-volume laboratories to continue entering data manually into a web portal, provided that the system is straightforward.

However, many laboratories are making significant investments into their information technology infrastructure with the addition of LIMS and data integration tools such as Rhapsody, BizTalk and others. Additionally, many are developing the capability to transmit laboratory results securely via national standards such as CDC's PHIN MS or the National Health Information Network (NHIN) Direct. (CDC, 2011; Direct, 2013) FDA's data exchange strategy should include tools and approaches that will allow these laboratories to share their data with little, if any, extra steps. Solutions should provide the capability for these laboratories to use the information already contained in the LIMS with no need for double data entry.

Food and feed-testing laboratories face many of the challenges that the PFP identified as obstacles to an IFSS. The heterogeneous, siloed systems of each laboratory, in some cases, of each laboratory section, and the unharmonized, non-standardized data in each system preclude interoperable data exchange. To meaningfully share data would require significant and time-consuming translation and transformation of the data. In addition, concerns over security and ownership of the data hinder the development of constructive relationships and timely data sharing.

The food safety community's current focus is the establishment of standard equipment, testing and methods in food and feed-testing laboratories; in the opinions of some FDA officials, this processual standardization must necessarily precede data standardization. FDA, in partnership with APHL, AAFCO and AFDO, is assisting many laboratories to seek ISO 17025 accreditation, which will ensure that that laboratories use accredited processes to test, verify and document results. The cooperative agreement between these organizations is developing tools, documentation, training courses and a national plan for attaining accreditation. FDA's push towards accreditation suggests that FDA plans to continue, or even expand, its contractual work with state laboratories and to use results from accredited laboratories as the basis for regulatory action. While data exchange is not a primary focus in this push, it is undoubtedly a key component of any long-term cooperation between FDA and state laboratories.

eLEXNET

Overview of database

FDA built eLEXNET in 1999 as “an integrated, secure network that allows multiple government agencies engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses.” The goal of eLEXNET is to enable “health officials to assess risks, analyze trends, and provide the necessary infrastructure for an early-warning system that identifies potentially hazardous foods.” (eLEXNET, 2013) When eLEXNET was implemented in 2000, it became one of the few databases that pools food-testing data from multiple state laboratories.

Currently, nearly 300 laboratories have users registered with the database. This number includes local and state laboratories, as well as regional FDA laboratories. In addition, the data from state laboratories that perform contract inspections for FDA is copied from FACTS to eLEXNET on a daily basis. Some USDA programs also send data to eLEXNET. For example, the USDA's Pesticide Data Program (PDP) and Microbiological Data Program (MDP) have both shared data with eLEXNET. Both programs are cooperative agreements that USDA maintains with several states to perform certain monitoring. USDA discontinued MDP at the beginning of 2013. The PDP is still active but has not uploaded data to eLEXNET since 2010.

In the PFP IIT WG's 2010 review of the functionalities of seven national food safety databases, including eLEXNET, eSAF, RFR, RES, and PulseNet, eLEXNET compared favorably to other systems by offering such features as training and user guides, scheduled reports and content notifications, ad hoc reports, and the ability to load and store any type of file. (PFP IIT 2010) The system was originally developed in a cloud environment and operates on an Oracle platform. For security purposes, roles determine the options available to each user. As an example, only FERN laboratories can see or access the FERN PT tab on the eLEXNET main page. The eLEXNET interface allows users to generate pre-configured or “canned” reports. These canned reports allow users to quickly search on default search criteria, such as date submitted, date collected, or laboratory name. Alternatively, users can create ad hoc reports to search on many additional fields, such as testing date. Search results can be exported in XLS, CSV and PDF formats.

Several of those interviewed reported that the eLEXNET team is knowledgeable and helpful, and the documentation for implementing data exchange with eLEXNET is straightforward. Representatives from eLEXNET provide on-site training and remote assistance. Topical training sessions are offered on a quarterly basis and are available to individuals on demand.

Data Import

Laboratorians can submit data to eLEXNET using one of three methods. First, they can enter data manually through a web portal, one record at a time. Each record consists of four forms (i.e., sample, test, action taken, and result). Second, they can upload XML or XLS files through the web portal. The eLEXNET system can accept data from any LIMS or database, provided that the file adheres to the specifications of the eLEXNET template and the data has been mapped to eLEXNET terms. A third option allows laboratorians to transmit the XML or XLS file via HTTPS to eLEXNET using a

semi-automated LGX utility. The utility is available for installation from the eLEXNET outreach team. The laboratorian must still generate an XML or XLS file from their systems and deposit it into a designated folder, though some savvy informaticians have automated this step for their laboratory as well. The LGX utility retrieves the file from the folder and transmits it to the eLEXNET database. Starting the utility requires running a start.bat file, but eLEXNET encourages laboratories to automate this step with the Windows Task Manager. The XML or XLS file upload and LGX utility capabilities are part of eLEXNET's Data Exchange (DX) Program, which is dedicated to developing convenient ways for laboratories to exchange data with FDA's database. Until recently, the eLEXNET team would also work with a laboratory to install a custom application that pulled data from the LIMS and transported the data via a secure HTTPS protocol. This mechanism did not give laboratories much control over the data that was submitted. In addition, installation of the application required express consent from the business program. Given these concerns, eLEXNET discontinued this service for onboarding laboratories in early 2013, though laboratories with a custom client already installed continue to submit data through this channel. Currently, 35 laboratories participate in electronic submission of data to eLEXNET.

When laboratories using the legacy custom clients upgrade their internal systems, the custom link to eLEXNET is severed, often without the laboratory being aware of the problem. At this point, they need to work with eLEXNET to re-implement a data exchange solution. While the eLEXNET team helps the laboratory move to an automated Excel or LGX solution, the laboratory submits data manually or via an Excel spreadsheet. For laboratories that lack the technical support and capabilities to implement an alternative data exchange solution, the custom client remains an option, though usually the laboratory opts to move to the modern solution.

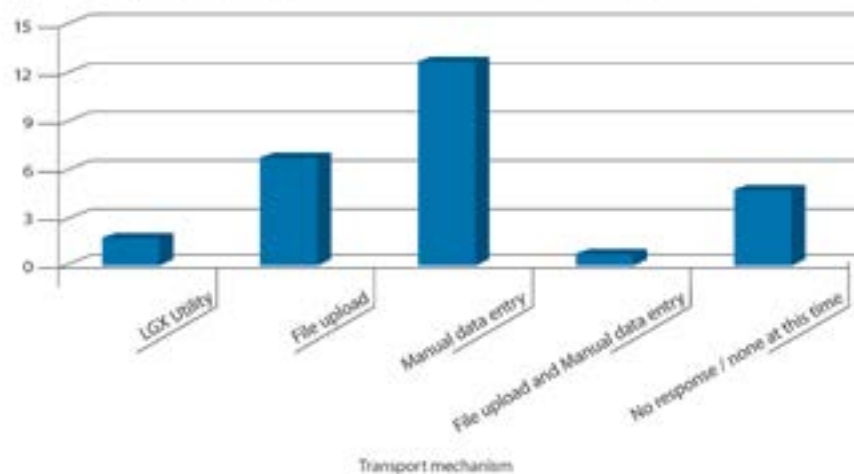
Data elements and standards

For each test, eLEXNET is capable of capturing over 100 different data fields; however, only 20 fields are mandatory. Required fields included laboratory name, unique sample ID, product name, collection date and location, analyte and test results. Laboratorians must map their local codes to FDA official terms for product code and analyte code. The eLEXNET terms are consistent with terms used in FACTS. To APHL's knowledge, eLEXNET does not use any other data standards at this time. Currently, there are no data elements that reflect dynamic data quality to support data validation for individual test batches.

Current Use Trends

Laboratories have no regulatory obligation to submit data to eLEXNET, though regular submission is a stipulation in some of FDA's cooperative agreements with local and state laboratories. Interview and survey responses regarding the frequency and content of eLEXNET data submissions revealed wide variation in practice. In terms of frequency, some submitters, such as the FDA FACTS system, add data to eLEXNET on a daily basis. Other submitters add data only intermittently. In an extreme case, the USDA PDP has not sent data to eLEXNET since 2010 (when the 2008 data was uploaded). For many laboratories, submission frequency depends on testing volume, and may vary from once a month to several times a week. Some laboratories submit data on a fixed schedule, usually once a week or monthly. Others report results as needed or "when practical to do so." According to the eLEXNET outreach coordinator, most laboratories update once a week or every day.

Figure 6: Transport mechanisms for adding data to eLEXNET



Of the surveyed laboratories currently sending data to eLEXNET, half submit data to eLEXNET manually (see Figure 6). Eight laboratories upload files, and 3 use the eLEXNET's LGX utility. One laboratory indicated that it enters data both manually and by uploading files. Five of the surveyed laboratories either provided no response or indicated that they do not contribute data at this time.

In terms of content, FACTS and the PDP upload all tests and results data to eLEXNET. State laboratories tend to send data for testing that fall under the purview of a particular contract or cooperative agreement. One state laboratory that APHL interviewed routinely sends results for the four most common analytes (i.e., *Listeria monocytogenes*, *Salmonella*, *Campylobacter jejuni*, and *E. coli*), but will soon expand the amount of data sent to comply with the requirements of a recent grant. Twelve of the surveyed laboratories (40%) report all food-testing results to eLEXNET, though one laboratory indicated that this is only the case for a specific list of analytes. Half of the laboratories (50%) upload proficiency testing results to eLEXNET (it should be noted that FERN laboratories are obligated to upload all FERN proficiency testing data to eLEXNET). Sixty percent report food surveillance testing results. Laboratories were less likely (40%) to report outbreak food-testing results. One laboratory reported that it uploads only positive results.

Many laboratorians voiced their organization's concern regarding the true 'de-identification' of the sample source in food/feed testing. For example, removing the manufacturer's name is a common practice but the zip code where the sample was taken could be sufficient to identify the location of a plant site. This major concern leads to reluctance by organizations to share test results during potential outbreak situations for fear that a food production site might be identified (correctly or not) in their jurisdiction. Such security concerns can be an obstacle to sharing data with the database at all and in a timely fashion.

Few laboratorians interact with eLEXNET apart from uploading data. Most do not use eLEXNET as an analytical tool to run reports or queries. An important exception is a Quality Manager whose laboratory uses MS Access to track samples. She supplements the database's capabilities by running reports on eLEXNET to review activities within her own laboratory over time. She rarely queries data from other regions or states.

In 2010, the PFP IIT WG surveyed local, state and federal agency food officials regarding their use of certain systems, including eLEXNET. Among local food officials, none reported using eLEXNET; 28% of state food officials and 20% of federal food officials reported using eLEXNET. Respondents did not indicate whether this “use” was primarily data import or analysis. (PFP IIT 2010)

APHL’s interviews identified a limited number of end users at FDA and in PHAs. An end user in the FDA’s Center for Food Safety and Applied Nutrition (CFSAN) in the Office of Compliance attested to using the system weekly, or even daily, to review data on pathogens, environmental samples, mycotoxins, antibiotic residue in seafood, and pesticides. In addition, a USDA FSIS FERN regional coordinator reported using the system about once a year to review regional food-testing trends. The coordinator noted that USDA is developing a new data entry application to improve and streamline the manual entry of specimen information and the associated test results. This data entry application is expected to supersede eLEXNET’s manual entry module for FERN participants.

Preparing eLEXNET for Its Role in an IFSS

As part of its discovery phase, APHL identified areas where FDA may choose to focus improvements to eLEXNET to better prepare the system for an integral role in an IFSS. The eLEXNET Steering Committee at FDA already has several improvements in progress. FDA has begun an effort to improve the quality of existing data, and is standardizing the data exchange mechanism of laboratories electronically sending food-testing data to eLEXNET. The fact that each laboratory performs and stores data differently and has a different IT infrastructure and data sharing capabilities can complicate onboarding and setup. Using a single standard procedure for data mapping with laboratories will reduce the cost and time it currently takes to onboard a laboratory. Laboratories will be able to control, view, and update their mapping, enabling laboratories to more efficiently track and implement changes. As a part of this effort, eLEXNET released a new Excel template with internal validation for laboratories to use to prepare data for upload in April 2013. The eLEXNET team is also working with several LIMS vendors to include an optional module in the LIMS that will generate an appropriately formatted file to send to eLEXNET. Feedback received during interviews indicates that these improvements have not gone unnoticed; users have observed a significant (positive) difference in data quality over the last several months. The improved data quality has enhanced their analyses.

Uploading Data

Capacity

Many of those interviewed reported that the manual data option available through eLEXNET’s web portal is a tedious process. A survey of seven national databases by the PFP IIT WG reported that entry of a single record into eLEXNET may take on average between 30 and 60 minutes to complete. (PFP IIT WG, 2010) However, internal surveys by eLEXNET indicate that a better estimation is 7 to 10 minutes per record, and usually no more than 15. Each of the four forms takes a user between 1 and 3 minutes to complete. Entries that contain supplemental information, such as Limit of Detection (LOD) and Limit of Quantitation (LOQ) may take an additional 1 to 2 minutes per test. Given that more than half of laboratories surveyed by APHL enter data manually, the process should be as efficient as possible.

Many laboratorians upload data as XLS or XML files, rather than, or in addition to, adding data manually. Each laboratory has its own process for generating these files in an approved eLEXNET format, and some interviewees expressed impatience with the mapping process. At times, data submitters clean up data manually or perform redundant cut and paste steps before sending the data.

Some data submitters with bigger data sets reported problems uploading large file sizes to eLEXNET. The USDA PDP's large data set, consisting of 12 to 13,000 samples, each with 200 analytes, needs to be broken into up to 1,400 separate files to upload to eLEXNET. Similarly, a LIMS administrator at a state agricultural laboratory limits uploads to about 300 samples per file because eLEXNET has rejected larger files. While this may not affect laboratories with small testing volumes, the limited capacity of eLEXNET to accept large file sizes may deter some laboratories from uploading data regularly, particularly if such uploads are purely voluntary.

FDA is aware of the need to improve the data exchange process, and is currently in the process of addressing several of these issues.

Message Exchange

Calls by the ITF, the PFP, and other community groups for fewer data silos and more data sharing between collaborating food safety partners suggests that the current point to point approach to interfacing laboratories with eLEXNET should be reevaluated. As the number of organizations contributing data to eLEXNET increases, the maintenance of the point to point interfaces also grows. From the laboratory's perspective the corresponding problem exists as the number of organizations requesting data grows, and the number of point to point interfaces which the laboratory has to support also increases.

The trend among these food safety partners, and among the data exchange marketplace in general, is toward standardized message format and content. The new regulations in the healthcare industry around electronic medical records and health information exchanges have greatly increased the adoption rate of this approach. At this point, eLEXNET does not support HL7 message exchange. Based on conversations with the eLEXNET team, there are no technical issues preventing the addition of this functionality to eLEXNET. While it may not be expedient for some laboratories with small testing volumes to transmit electronic messages, nevertheless, some users expressed a strong interest in exchanging data with eLEXNET via more automated message exchange such as HL7. FDA may consider developing alternative transport routes through Direct or PHINMS, which are becoming increasingly popular in health information exchange. Laboratories may be able to implement a higher degree of automation with these routes, thereby making data exchange with eLEXNET easier and more regular. Moreover, by syncing with these trends FDA would enable laboratories to use a single route to transport messages to multiple recipients.

Data Availability and Consistency

The Public

Occasionally, the public can access the data contained in certain federal databases. Many of

these databases rely on electronic data exchange and strict data standards to present the data in user-friendly interfaces. For example, the PHLIP data help populate CDC's FluView, an application accessible to the public on the CDC's website, and that presents weekly influenza activity by state. Similarly, the public can use the Envirofacts' Application Programming Interface (API) to search the EPA's Safe Drinking Water Information System (SDWIS) for contaminants in their drinking water. SDWIS is populated by state and local laboratories that add testing results to the database. (EPA, 2013) Comparatively, the public cannot query data in any of the seven food safety databases reviewed by the PFP IIT WG (i.e., eSAF, the North Carolina Recall System, RES, RFR, eLEXNET, PulseNet, and FoodSHIELD). (PFP IIT WG, 2010)

Investigators

While public health mandates require public health laboratories to report testing and results for certain pathogens and illnesses, there is currently no broad-based mandate or requirement for state and local organizations to report laboratory results from food and feed testing. This lack of federal regulation has resulted in a patchwork of memorandum of understanding (MOU) and cooperative agreement contracts between the FDA and a limited number of state agencies. Individual MOUs or cooperative agreements may include requirements for laboratories to upload data for certain test results to one or more national databases. Laboratories sometimes upload data during the period of the MOU or cooperative agreement and then stop due to changes in the contract. These contracts are transient and change frequently, and it is not unusual for a laboratory to be working under multiple contracts for multiple organizations, each with different reporting requirements.

From a practical point of view this patchwork of legal requirements has resulted in confusion and uncertainty in many of the participants in the data exchange process. During interviews, almost everyone indicated a lack of understanding as to when and why laboratories share laboratory results.

Furthermore, the reluctance of some laboratorians to share data during an active investigation limits the reliability of the data in eLEXNET for investigators. As one of the few databases that aggregates food-testing data from state laboratories, eLEXNET can be a powerful tool in an IFSS, but only if laboratories add data regularly and do not withhold data during an investigation.

The result of this reluctance and this patchwork of contracts between the states and FDA is an incomplete, untimely, and inconsistent set of test results from a limited number of states. During any given time period, the test results from a particular state may or may not be available in eLEXNET. This makes performing meaningful data analysis difficult at best. For example, a search of all positive Salmonella samples from a specific state during the summer of 2010 might find numerous records while the same search during the summer of 2011 might find none. The reason for the differing search results could easily be that the cooperative agreement for that state ended in 2010 so no data was uploaded in 2011. Unless the person performing the search has detailed knowledge of the 'patchwork' of contracts across the country, incorrect conclusions could be drawn. The reason may also be a delay in uploading the data or inconsistent metadata in certain fields. With only 20 required fields (out of more than 100 possible fields), the data that a user chooses to add to a record may vary widely, which can impair the sensitivity of searches. In addition, when a product code is not available, laboratories can enter free text that eLEXNET staff then map to the appropriate code; until this manual mapping occurs, search results may be incomplete.

The difficulty of capturing the data elements that analysts need begins with the growers or producers themselves. The traceback data provided by producers may be incomplete, thus limiting the ability of regulatory agencies to draw useful conclusions from surveillance data and take actions to assure food safety. The practice of the food industry to mix fresh produce from multiple sources with little record keeping, for example, can make it impossible to determine the grower or even the state or country from which a contamination has originated.

The choices that laboratories make about how to manage and process the erratic data they receive further complicate the searchability of the data. For example, some laboratories indicate that the sample originated from a vegetable, canned (verses fresh or frozen). It may be more helpful for an analyst to know the kind of vegetable than the form. The granularity of terms should reflect the information that investigators are most likely to need. One survey respondent described the following scenario in which enhanced searching capabilities would be useful: “I just found Salmonella in an imported spice – Have any other laboratories reported a similar finding in this product?” Such information may be searchable with custom reports, and some end users have become adept at building these ad hoc reports and have saved these customized searches to their accounts. At least one end user confessed to relying almost exclusively on ad hoc reports.

Consolidating data residing in disparate systems can be a significant obstacle to performing tracebacks during an outbreak. In 2012, for example, it took one State Department of Health seven months to complete the traceback investigation on 56 related cases of Salmonella Heidelberg. A database that efficiently and effectively consolidated these data routinely would be an advantage to investigators.

Information collected during APHL’s discovery period indicates that eLEXNET is currently used primarily for retrospective studies rather than early detection and prevention of disease outbreaks. As noted in this report, this is due primarily to the oft-times lengthy intervals between the completion of testing and the uploading of the data. For the system to be viewed as a valuable resource in emergency response situations, the data must be available in hours or days rather than weeks or months. eLEXNET may be able to play a key role in an IFSS, provided that the data is available and usable when investigators need it.

Chapter Summary

The informatics capabilities of food and feed-testing laboratories vary widely. These laboratories use an array of strategies to fulfill their information management and data exchange processes. Any strategy for improving data exchange between state laboratories and eLEXNET must take this diversity into account. It is highly likely that FDA will need to offer laboratories multi-tiered solutions to accommodate their current capabilities. As part of this strategy, FDA may choose to enhance the eLEXNET system by addressing specific technical and policy issues. In particular, the timeliness and consistency of the data in eLEXNET are an issue for investigators. In the next section, APHL offers some possible next steps for confronting these challenges.

Suggested Next Steps

The gaps identified during the discovery phase concern capabilities at the laboratories, the comprehensiveness of the data submitted to eLEXNET, and the usability of the data in the system. Some of these gaps require technical solutions; many are policy-related. Which of these gaps is the most critical to address depends on FDA's vision of an IFSS. Items to consider in this vision include:

- Role of state laboratories vis-à-vis FDA regulatory action.
- Primary role of eLEXNET: to facilitate surveillance, or to support an emergency response system?
- Data quality v. data volume: strict data standards would yield fully interoperable, clean data that are easy to manage and analyze, but would likely lead to lower adoption rates with fewer laboratories contributing data. Less strict standards would keep participation high but the data would not be as clean.

The suggestions offered below assume that FDA would like to leverage limited resources to make a valuable impact on the food safety system. The suggestions are divided into steps that FDA can take in the short term (i.e., within the next two years) to realize improvements in data interoperability, and long-term objectives that FDA can work towards over the next five to ten years. As noted in earlier sections of this report, significant efforts have already been made in the creation of an IFSS. Much work has also been accomplished in related areas such as the exchange of PHL laboratory results. In order to move FDA systems forward as quickly as possible, APHL based the suggested next steps on the accomplishments of these earlier efforts.

Second Year

During the second year of the cooperative agreement with APHL, FDA can take important steps towards improving data exchange between state laboratories and FDA systems. These steps include 1) leveraging the National User Group to obtain community consensus on planned improvements; 2) identifying the minimum data elements required for adequate data exchange; 3) establishing data standards for the electronic exchange of food and feed-testing laboratory results.

User Group

The National User Group that APHL convened during this discovery phase presents a unique opportunity to build an advisory body for the food and feed-testing laboratory community, but to have a broad impact on the community and on developing standards, the group needs FDA's support and recognition. In addition to serving as an open forum for discussion, the group, with representatives from FDA, APHL, AFDO, AAFCO and state laboratories, can offer guidance on initiatives that FDA chooses to pursue. Many group members are subject matter experts in food and feed-testing and data exchange, and can offer the benefit of their experience and expertise as the group identifies minimum data elements and standards. In a broader context, the User Group can also serve as an information hub for informatics-related topics that may need to be shared with the food safety

community.

Furthermore, the group's advisory role would allow state laboratories to participate in finding solutions to community problems. Laboratory representatives involved from the beginning in the development of data standards and transport mechanisms will support these standards within their own laboratories, and other laboratories will be more likely to accept standards if laboratorians are involved as decision-makers.

Data Standards

It is important to note that the challenge of sharing data across non-integrated systems is universal, and several groups have already suggested strategies for dealing with this challenge. For example, NORC, in its review of the information technology infrastructure of state and local health departments, indicated two possible paths forward: use of a common data model and the adoption of data standards, well-defined interfaces, and common messaging standards. The report concluded that the path to a common data architecture at this time is at best unclear. It suggested the use of programs, policy, and funding opportunities to encourage consistent data content, data models and messaging standards in the near term. (NORC, 2013) APHL is suggesting similar steps forward for food and feed-testing laboratories.

On a technical level, the eLEXNET system is adequate. The system supports manual entry of data along with secure batch file uploads, and the eLEXNET team has steadily been making improvements to the legacy system and to the quality of the data. Future improvements to the system should concentrate on allowing users to upload larger data sets without stalling the system. User notification of successful file uploads following data validation is also desirable. In addition, the manual data entry function should be redesigned so users can enter data more quickly. While there are some technical issues that the team needs to resolve, overall, the system functions well and features an easy-to-use reporting interface.

From an informatics perspective, interoperability, or the ability to exchange useful data across systems, poses the greatest challenge to meaningful data exchange between state laboratories and FDA. In many cases, the data sent from multiple laboratories to eLEXNET cannot be searched and analyzed in a meaningful way as a single set of integrated data. For truly interoperable information transfers, all parties involved in the data exchange must agree on the semantics, syntax, and transport of the message. Each of these three levels of coordination is discussed further in the sections that follow.

Semantics

For interoperable data exchange, sender and receiver must agree on the signification of the words used in the message, in other words, on the vocabulary. For example, if the sender designates a patient's gender as "Male" or "Female" but the receiver uses the terms "M" or "F," the receiver's system may not be able to process the sender's message correctly. Another sender might indicate gender with a yes/no box for "Male." If the sender's gender codes enters the receiver's system without being standardized, the end user would need to search on all possible variations to ensure

a comprehensive search. Vocabulary presents a significant impediment to interoperable data exchange. Even when coding for the same concept, if the receiver's system does not recognize the sender's code, the exchange risks losing the information in translation. Agreed-upon vocabulary standards ensure that the sender and receiver understand the information that is transmitted. Local systems can still use their own coding, provided that the LIMS or integration broker or IT administrator maps local codes to standard codes before the information is transmitted. The receiver's local system will be able to read the message using the same mapping process in reverse.

Due to the diversity of samples and testing performed in the food safety system, a number of vocabulary standards may need to be considered, and the comprehensiveness of existing standards will need to be assessed. For example, Logical Observation Identifiers Names and Codes (LOINC) is a coding system for laboratory tests. If this system does not cover the majority of tests that are performed in food and feed-testing laboratories, it may be necessary for a vocabulary workgroup to develop additional codes. Other vocabulary standards include the Chemical Abstracts Service (CAS) Registry, which describes more than 72 million organic and inorganic substances and 64 million sequences. The Systematized Nomenclature of Medicine (SNOMED) coding system is predominantly used for clinical results. SNOMED coding is often used in microbiological testing, however its applicability to other types of food testing may be limited. For product codes, appropriate vocabulary standards will need to be assessed. It may be possible to start with FDA's official term list and determine whether this list provides laboratorians and analysts with sufficient granularity, how well it maps to local coding systems, and how easy it is to use.

Syntax

The next level of coordination is syntax, or message structure. The receiver must recognize the sender's message structure to be able to parse the message and, if necessary, transform the message for import into the receiver's system. In other words, the receiver has to know where to look in the sender's message for each element of the report, whether collection site, sample type, test method, result, etc.

All of the information in an electronic message, whether mapped to vocabulary standards or not, must be structured in a way that will be intelligible to the receiver. To facilitate data integration, data exchange partners must agree on the fields to be exchanged, the labels for those fields, the order in which they are conveyed, and the punctuation used to separate the various parts of the message. To do this, laboratories need a data standard that creates a formatted data deliverable which is accepted and recognized by their data exchange partners. Some organizations are already developing electronic data deliverables (EDD) that may satisfy multiple reporting requirements and/or recipients. For example, EPA, in collaboration with APHL, is developing an EDD for environmental laboratories. (APHL, 2012) To the extent possible, FDA should take advantage of existing efforts and leverage the work of other standards development organizations. The use of widely-recognized data standards will reduce the burden on states that have to report to multiple agencies, and will facilitate data exchange between agencies, as well as between states.

FDA has been moving towards a rational questionnaire approach, with standard forms increasingly used for registration systems, compliance, and inspection systems. Such forms make IT integration

and harmonization easier, and are a first step to developing data standards. The same approach can help laboratory data exchange by streamlining the sequence and format of data that laboratories report. The eLEXNET team has already introduced templates for standardizing data exchange, and requires laboratories to map to these templates when submitting data.

Minimum Data Elements

Implicit in any discussion of syntax and semantics is the identification of the information to exchange. At a minimum, what data needs to be transmitted from food and feed-testing laboratories to FDA? It is critical to define the required data elements, the basic structure of those elements, and how they relate to each other. These data elements should include the essential data points that laboratories routinely report to state and federal agencies. A definition of these minimum data elements must also take into consideration the information that investigators need for surveillance or during a foodborne outbreak response. Often, the identification of minimum data elements is complicated by particular programmatic needs for data that may not be laboratory-driven, such as demographic or geographic data.

Other programs have developed sets of minimum data elements specific to their programmatic needs. The LRN identified a set of minimum data elements for its partners, and has had success communicating requirements for bioterrorism and chemical terrorism data exchange with several of the larger LIMS vendors. The vendors are able to configure the requirements in the LIMS and provide them to the LRN laboratories. This ensures that 1) the LIMS can capture the required data elements and 2) the elements are consistently captured in a way that supports the standard message. This vendor cooperation may be a model that FDA can follow, though, given the number of LIMS deployed in food and feed-testing laboratories, FDA will have to consider carefully the LIMS vendors with which it should work.

Some minimum data sets include quality control data that provide data validation for decision-makers. A “result” without any reference to sample batch or the analytical sequence of spikes, blanks, etc., leaves important decision makers without support of the quality of the data. The addition of one or two fields, such as batch ID for the analytical run or other QC parameters, can furnish individual results with a level of accountability. The inclusion of such measurement quality objectives is an important consideration when developing data standards.

Ideally, any vocabulary or data standard that the food and feed-testing laboratory community develops would be applicable across programmatic lines, allowing laboratories as senders to generate reports in a single message format that can be submitted to multiple recipients, such as eSAF, USDA and eLEXNET. It may be possible to leverage existing data standards, and the first step would be to identify the most important fields to standardize and then determine if available standards are applicable to food testing.

For the second year of the cooperative agreement, APHL proposes concentrating the User Group’s efforts on developing vocabulary and standards to govern the semantics and syntax of laboratory results messaging. Data exchange partners must agree on the content of the message before they consider transport mechanisms; this clarification of the content should also precede any policy initiatives to increase the amount of data submitted to eLEXNET. If FDA is going to consider

nationwide reporting requirements, laboratories should be given clear specifications of what to report and how.

Action Items

During the second year of the cooperative agreement with FDA, APHL proposes to:

- Set up a community of practice consisting of members from the National User Group (both laboratorians and data analysts) to develop a set of minimum data elements required for meaningful data exchange.
- Identify Minimum Data Elements for message exchange.
- Identify existing vocabulary and data standards and begin development of standards specific to food and feed-testing laboratory reporting. It may be beneficial to bring in a subject matter expert to advise the User Group during this process.

Next Steps

As data standards are developed, APHL proposes a series of next steps to build on the second year activities discussed above. First, FDA must address the third element of interoperability: transport. Given the diversity of laboratory capabilities, APHL recommends a multi-tiered approach to data transport. Second, FDA must define a strategy for increasing the amount of data in the eLEXNET system and improving the timeliness of that data. From a policy perspective, this effort may entail incentives for data submitters and/or the introduction of obligatory reporting requirements. Next, a constrained pilot involving one or two laboratories would allow FDA to implement the agreed-upon vocabulary, data standards, and transport mechanisms on a small scale and position itself for a national rollout in the future.

Transport

The technical issues of message transport mechanisms, such as the specific schemas to use and how to delimit the message content, will need to be considered in the context of the minimum data elements and data standards developed in Year Two. The specific implementation approach chosen will depend on many factors. A key consideration is the message transports being used by the laboratory's data exchange partners. The survey conducted during this discovery period found that laboratories reported test results to multiple organizations other than eLEXNET. Finding a consensus solution to the transport issue will be challenging and will require collaboration between all stakeholders.

As FDA pursues the development of electronic messaging, filtering these messages through the APHL Route-not-Read Hub may offer some technical advantages. The Hub facilitates data exchange between state PHLs and CDC (in the context of PHLIP and LRN), as well as between a number of other messaging partners. It exchanges data predominantly via PHIN MS, but is also developing Direct capability. The Hub can process messages in a number of formats, including HL7 and XML.

Furthermore, the Hub's FISMA-moderate certification ensures secure data transport, and may assuage some of the security concerns that FDA has with regards to exchanging sensitive data. Most significantly, the Hub reduces the burden of point-to-point contacts. Rather than a separate connection with each laboratory, eLEXNET would maintain a single point-to-point contact with the Hub, which would deliver messages from all data submitters. A number of state laboratories have already established a connection with APHL's Hub, and therefore, in certain cases, the effort involved in adding messages would be minimal. In the future, the Hub may be able to transform the laboratory's message for consumption by many reporting agencies.

Security

Security and privacy concerns may erect barriers to data sharing. Establishing a data-sharing agreement for all eLEXNET participants may alleviate some of these concerns and foster a more open and trusting environment in which to exchange data. This is an important goal, but one that will take time, and will require policy changes. The Data Use and Reciprocal Support Agreement (DURSA) that directs data sharing policies among users of the Nationwide Health Information Network (NHIN) may provide a useful model for a blanket data sharing agreement. While the DURSA's etiquette rules for message transactions need to be re-phrased to apply to loading into and accessing content from a database, the arrangements described in the DURSA resemble the scenario of many eLEXNET users:

- Relationships of participants differ, with some having no relationship at all;
- System access policies differ by participant;
- Each participant has generic security responsibilities to create a safe environment and notify partners of breaches;
- Participants may use the database and the data only in the way intended by the agreement;
- Participants are licensed to use common participant resources; and
- There is a formal process for approving/dissenting to changes to the performance and service specification (Office of the National Coordinator, 2011)

FDA should consider a data sharing agreement to dismantle some of the obstacles for states and federal agencies to share data with eLEXNET. One consideration is that the necessity of executing a DURSA would add one more disincentive to using the database. Therefore, the advantages offered by this data exchange would have to supersede this reticence.

Policy

This discovery document deals primarily with identifying technical issues and proposing approaches to solutions for the effective exchange of food safety data. During our conversations with laboratory personnel, FDA contacts, and members of the User Group, the disparity in food safety reporting across the country was widely acknowledged. CIFOR's Guidelines for Foodborne Disease Outbreak

Response contains a good overview of the legal framework used during outbreak and surveillance activities. (CIFOR, 2009) As mentioned earlier, the current patchwork of reporting requirements severely limits the effectiveness of eLEXNET. This is particularly true in cases of foodborne disease which require coordination across multiple jurisdictions. Efforts by the FDA to establish more uniform regulations related to data reporting could greatly enhance the value of eLEXNET as a primary repository for food safety data. Policy changes and their implementation are longer-term goals reaching beyond the scope of this project. In the near term, FDA should consider expanding to all states the use of cooperative agreements with specific laboratory data reporting requirements as a way to ensure better coverage and consistency within the testing results stored in eLEXNET.

Pilot / Technical Assistance

Once FDA has developed satisfactory data standards, it may consider conducting a constrained pilot. At this stage, FDA and APHL can work with one or two state laboratories to implement the standards and transport mechanism that the User Group develops with APHL. APHL can provide the laboratory with technical assistance to help map local to standard codes and generate a valid message. The pilot will test the interoperability of the data sent from the state laboratory to eLEXNET in terms of semantics, syntax, and transport. It will also assess whether the technical assistance model that APHL developed in the context of other informatics initiatives is suitable for implementing state-to-FDA data exchange.

APHL Informatics developed the technical assistance team approach to guide and support PHLs, PHAS and other data exchange partners. The team works with laboratory, technical, and epidemiology SMEs, both remotely and on-site, to assist with project management and business analysis; data standards and vocabulary harmonization; workflow analysis; and designing a technical architecture. This direct assistance has yielded successful results in a number of APHL Informatics projects, including PHLIP and ELR TA. Coordinated technical assistance teams may benefit food and feed-testing laboratories that are implementing electronic data exchange.

Additional Considerations

During the Discovery Period the project team had conversations with people associated in a variety of ways with food safety. Here are some of the salient points from those conversations:

1. Mandatory reporting requirements for food-related issues would greatly increase the uniformity and coverage of eLEXNET data.
2. Usage of eLEXNET as a primary data source for multi-jurisdiction efforts would increase if the data coverage across the country increases. FDA should consider developing presentations and training geared toward analysts and should reach out to local and state departments of health and agriculture when onboarding new laboratories.
3. State food and feed-testing laboratories are in the process of strengthening their informatics capabilities and are looking for guidance during this development phase.

4. Organizations at many levels are moving toward more standardized processes and are attempting to remove barriers to data sharing. Collaboration with the relevant organizations and standards development organizations could benefit FDA food safety initiatives.

Chapter Summary

The focus during the second year of the cooperative agreement on working with the guidance of the User Group to establish standards for data exchange between state laboratories and eLEXNET represents a small step toward an IFSS. Major efforts at the national level to reduce barriers between existing silos of data are underway. Leveraging these efforts will benefit the current data exchange project. Additional steps toward fully interoperable systems will require collaboration with other groups within FDA and external organizations. Beyond solving these technical challenges, there are significant policy obstacles to address before eLEXNET can realize its goal of being the primary repository for food safety data.

Abbreviations

AAFCO	Association of American Feed Control Officials
AFDO	Association of Food and Drug Officials
APHL	Association of Public Health Laboratories
ASTHO	Association of State and Territorial Health Officials
ASTM	ASTM International, formerly known as the American Society for Testing and Materials
CAS	Chemical Abstracts Systems
CDC	Centers for Disease Control and Prevention
CIFOR	Council to Improve Foodborne Outbreak Response
EDD	Electronic Data Deliverable
eLEXNET	Electronic Laboratory Exchange Network
ERLN	Environmental Response Laboratory Network
eSAF	Electronic State Access to FACTS
FACTS	Field Accomplishments and Compliance Tracking Systems
FDA	Food and Drug Administration
FERN	Food Emergency Response Network
FSIS	Food Safety Inspection Service
FSMA	Food Safety Modernization Act
ICLN	Integrated Consortium of Laboratory Networks
IFSS	Integrated Food Safety System
IIT WG	Integrated Information Technology Workgroup
LOINC	Logical Observation Identifiers and Codes
LRN	Laboratory Response Network
MARCS	Mission Accomplishment and Regulatory Compliance Services
MQO	Measurable Quality Objectives
NHIN	Nationwide Health Information Network
NORC	National Opinion Research Center
NORS	National Outbreak Reporting System
PFP	Partnership for Food Protection
PHII	Public Health Informatics Institute
PHIN MS	Public Health Information Network Messaging System
PHIS	Public Health Information System
PHA	Public Health Agency
PHL	Public Health Laboratory
SDWIS	Safe Drinking Water Information System
SNOMED CT	Systematized Nomenclature Of Medicine – Clinical Terms
USDA	United States Department of Agriculture

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This document was made possible by the contribution of many individuals, including volunteers, contractors, subject matter experts, workgroup members and others. The members of the project team primarily responsible for the content of the discovery document are listed below.

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Interviews

Over the course of this discovery period, APHL conducted more than two dozen interviews with state laboratory directors and IT staff, stakeholders in FDA's Office of Regulatory Affairs and the Center for Food Safety and Applied Nutrition, eLEXNET contractors, representatives from USDA and other subject matter experts. Below is a list of the organizations, programs and individuals that assisted

APHL & FDA Contractors

APHL during these interviews.
 Center for Food Safety and Applied Nutrition (CFSAN)
 MARCS project team
 Office of Regulatory Affairs
 eLEXNET contractors

State Laboratories

Connecticut Agricultural Station
 Florida Bureau of Public Health Laboratories
 Iowa State Hygienic Laboratory
 Minnesota Department of Agriculture
 New York Department of Agriculture
 Texas Department of State Health Services
 Washington State Department of Agriculture

Partnership for Food Protection

Integrated Information Technology Workgroup
 Laboratory Workgroup

Other agencies/organizations

Public Health Informatics Institute (PHII)
 USDA Food Safety and Inspections Service (FSIS)
 USDA Pesticide Data Program (PDP)

Other Subject Matter Experts

Jack Krueger, Consultant to APHL and former Director,
 Maine Health and Environmental Testing
 Laboratory
 Jean O'Connor, former Deputy Director, Oregon State
 Public Health Department

Survey

1. Please provide contact information for the person responding to this survey, including name, title, laboratory, phone number and email address.
 - Name
 - Title
 - Laboratory
 - Email Address
 - Phone Number
2. Your laboratory is a...
Please check all that apply
 - Federal laboratory
 - State laboratory
 - Local laboratory
 - Public health laboratory
 - Clinical laboratory
 - Agricultural laboratory
 - Agricultural laboratory
 - Chemist laboratory
 - Environmental laboratory
 - Other (please specify)
3. Does your laboratory use a laboratory information management system (LIMS)?
 - Yes
 - No
4. What system are you using to manage and record laboratory tests and results? Please check all that apply.
 - Paper (hard copy)
 - Microsoft Access
 - Microsoft Excel
 - Other (please specify)
5. Please indicate the LIMS that your laboratory currently has installed (i.e., vendor name and version). If the laboratory has multiple LIMS installed, please indicate the functional area that uses each LIMS.

6. Can your laboratory send and/or receive electronic messages for test results using agreed-upon standards and vocabulary for message creation and transmission.
 - Send
 - Receive
 - Send and receive
 - No messaging capability

7. In what formats does your laboratory generate these messages? Please check all that apply.
 - CSV
 - HL7
 - XML
 - Other (please specify)

8. Laboratories may use an integration engine to perform such functions as validating, filtering, and mapping data, converting local codes to standard codes, and generating valid message structures. If applicable, please indicate the integration engine that your laboratory uses.
 - Biztalk
 - Cloverleaf
 - Mirth
 - Rhapsody
 - Our laboratory does not use an integration engine
 - Other (please specify)

9. Please indicate all of the standard coding systems that your laboratory currently uses to describe tests, results, products, or other data. Please check all that apply.
 - CAS
 - LOINC
 - SNOMED
 - UCUM
 - FDA Official Term List
 - Other (please specify)

10. How does your laboratory report various data to recipients? Please check all that apply.
 - Hard copy
 - Email
 - Fax
 - PHIN MS

- Direct
- Web portal
- Other (please specify)

11. Which external organizations are the recipients of these reports? Please check all that apply.

- State public health agency or department of agriculture
- Local public health agency or department of agriculture
- A state public health laboratory
- CDC
- FDA
- USDA
- EPA
- FERN

12. Is your laboratory registered with eLEXNET?

- Yes
- No

13. Does your laboratory routinely report data to eLEXNET?

- Yes
- No

14. How frequently does your laboratory report results to eLEXNET?

- Immediately
- Daily
- Weekly
- Monthly
- Other (please specify)

15. What results does your laboratory report to eLEXNET? Please check all that apply.

- All food results
- Outbreak food testing results
- Food surveillance testing results
- Proficiency testing results
- Other (please specify)

16. What transport mechanism does your laboratory typically use to add data to eLEXNET?
 - LGX Utility
 - File upload
 - Manual data entry
 - Other (please specify)

17. Please indicate the reasons are you sharing data with eLEXNET. Please check all that apply.
 - Requirement of Cooperative Agreement with FDA
 - Requirement of Cooperative Agreement with USDA
 - Requirement of other funding source
 - Regulatory requirement
 - Policy of the laboratory
 - Other (please specify)

18. Is there anything that you would like to change about eLEXNET?

19. May we contact you if we need more information for our study?
 - Yes
 - No
 - Additional Comments

Data Exchange Initiatives

Sponsor	Other participating organizations	Initiative	Description	Stakeholders	Objective	Maturity	Timeframe	Source	Notes
FDA	State laboratories	eSAF/FACTS	eSAF is the only external system FDA maintains to exchange inspection info with regulatory partners. States that perform contract inspections for FDA enter data into FACTS via eSAF.	FDA and state inspectors and regulatory officials	Provide portal through which states can enter inspection data into FACTS	About 10,000 state inspections have been recorded in the system.		FDA, "Q&A: Food Protection Plan," 2013	
FDA	USDA Laboratories	Food Emergency Response Network (FERN)	Network of 170+ laboratories that can provide a coordinated response to a foodborne emergency.	FDA, USDA, laboratories	Integrate food-testing laboratories into a network to respond to emergencies involving biological, chemical, or radiological contamination of food	170+ member laboratories	Developed in 2004	Sciacchitano, 2003	
FDA		Mission Accomplishment and Regulatory Compliance Services (MARCS)	MARCS consists of diverse applications and services that streamline ORA business processes and workflows and provide better access to information. These software applications and services will be implemented on shared technology platforms.	FDA ORA	Full and complete integration of FDA ORA internal systems, including district offices and laboratories	In development	2011-present	SRA, 2012	
FDA	CDC, USDA	National Antimicrobial Resistance Monitoring System (NARMS)	FoodNet, USDA, and CDC laboratories test a designated number of animal, human, and retail meat samples for certain microorganisms (e.g., Salmonella, Campylobacter, E. coli); further testing is done to determine antimicrobial resistance	FDA, USDA, CDC	Monitor antimicrobial susceptibility among enteric bacteria from humans, retail meats, and food animals.	In production	Human component began in 1996; animal component in 1997; retail meat component in 2002	FDA, 2010	
CDC	APHL, PHAs	Electronic Laboratory Response Technical Assistance (ELR TA)	ELR TA offers technical assistance to PHAs to develop and establish ELR data flows with their laboratory partners.	PHAs, laboratories (PHLs, commercial, hospital, etc.)	Enhance the ability of PHAs nationwide to receive and process ELR	Received 60+ requests from 20+ jurisdictions	Launched 2012	APHL, "ELR TA," Undated	

Sponsor	Other participating organizations	Initiative	Description	Stakeholders	Objective	Maturity	Timeframe	Source	Notes
CDC	Palantir	Foodborne Disease Outbreak Investigation System (FDOIS)	FDOIS is powered by the Palantir Disease Response solution. CDC analysts have access to a special “user-friendly dashboard,” as well as mapping applications	CDC epidemiologists	Integrate datasets from diverse sources, including PulseNet, the NORS, and other sources (e.g., investigation details, questionnaires)	Fully operational. CDC has used FDOIS to investigate dozens of outbreaks and has coordinated outbreak responses with seven states	Launched 2010; currently in use	Palantir, Impact Study	FDA has plans to use Palantir Disease Response as their disease investigation and response infrastructure
CDC	FDA, USDA, state health departments	Foodborne Diseases Active Surveillance Network (FoodNet)	FoodNet, part of the CDC’s Emerging Infections Program (EIP), collects reports of infections from clinical laboratories in 10 states and conducts surveillance on 15% of the US population.	CDC, EIP sites	Monitor trends in foodborne illness over time and disseminate information about foodborne illness	In operation at 10 EIP sites	Began surveillance in 1996	CDC, “FoodNet,” 2013	
CDC	APHL, FBI, laboratories	LRN	Integrated networks of state and local public health, federal, military, and international laboratories that can respond to bioterrorism (LRN-B), chemical terrorism (LRN-C), and other public health emergencies.	CDC epidemiologists, FBI	Ensure an effective laboratory response to bioterrorism by helping to improve the nation’s PHL infrastructure	In production with 150+ laboratories	Became operational in 1999	CDC, “LRN,” 2013	
CDC	Local and state health departments	National Outbreak Reporting System (NORS)	NORS is a web-based platform that allows local, state, and territorial health departments to enter reports of enteric disease outbreaks, as well as waterborne outbreaks of non-enteric disease. NORS collects data on many types of outbreaks, including foodborne enteric illness.	CDC epidemiologists, outbreak investigators	Monitor enteric disease outbreaks	In operation	Launched 2009	CDC, “NORS,” 2013	Data collected includes date and location of the outbreak, the number of people who became ill and their symptoms, and the pathogen that caused the outbreak
CDC	APHL, PHLs	Public Health Laboratory Interoperability Project (PHLIP)	PHLIP is a collaborative effort between APHL and CDC to provide assistance with implementing viable electronic laboratory messaging solutions.	PHLs, CDC	Establish data flows between PHLs and CDC for electronic surveillance	In production with influenza electronic laboratory surveillance messages (ELSM)	2006-present	APHL, “PHLIP,” Undated	

APPENDIX F

Sponsor	Other participating organizations	Initiative	Description	Stakeholders	Objective	Maturity	Timeframe	Source	Notes
CDC	PHLS	PulseNet	Database managed by CDC that captures PFGE results for foodborne disease-related bacteria.	CDC epidemiologists, outbreak investigators	Identify clusters of foodborne disease that require intensive follow-up investigations	60,000 results entered per year; 160 clusters identified in 2012	1996-present	CDC, "PulseNet," 2013	
CDC	Palantir	System for Enteric Disease Response, Investigation and Coordination (SEDRIC)	Database developed by the CDC Innovation Office to integrate epidemiological, laboratory, and traceback data from a variety of sources.	CDC epidemiologists	Integrate datasets from diverse sources	200 users in 45 state/local health departments, CDC, FDA, USDA FSIS enter data into a web browser	National rollout anticipated in 2013	Williams, 2013	
CIFOR	APHL, PHLS	Epi/Lab Integrated Reporting project	Pilot of 1 model site and 3 pilot sites to develop combined epi/lab reports in standard format that will eventually allow reporting between jurisdictions.	CIFOR, state health department epidemiologists	"A domestic, open-source application ... that combines multiple laboratory data into a single report."	Pilot project		APHL, supporting CIFOR," 2013	CIFOR is also working on a cost-benefit analysis of PulseNet
EPA	Laboratories	ERLN	A network of public and private laboratories that can be ramped up as needed to support large scale environmental responses	EPA	Provide decision-makers with analytical data to identify chemical, biological, and radiological contaminants during nationally significant incidents	In production; most state PHLS participate in ERLN and submit analytical results electronically through WebEDR.	Launched 2008	EPA, 2009	
ICLN	LRN, FERN, ERLN, DLN, NAHLN, NPDN	Integrated Consortium of Laboratory Networks (ICLN)	An MOA establishes a multi-agency commitment to the integration of multiple laboratory networks	DHS, CDC, USDA, DOD, EPA, DHHS	Establish a framework for coordinated, integrated responses to major incidents, including acts of terrorism	In operation	2005-present	ICLN, 2012	

Sponsor	Other participating organizations	Initiative	Description	Stakeholders	Objective	Maturity	Timeframe	Source	Notes
National Center for Food Protection and Defense	FDA, USDA, APHL	FoodSHIELD	FoodSHIELD provides web-based tools that facilitate collaboration between regulatory agencies and laboratories and their affiliated workgroups.	Local, state and federal regulatory agencies and laboratories	Support regulatory agencies and laboratories in defending the food supply	In operation; 190+ workgroups using FoodSHIELD's web-based tools			
ONC/ S&I Framework	PHAs, Healthcare Providers, EHR vendors, CDC, FDA	Public Health Reporting Initiative (PHRI)	PHRI is working with Electronic Health Records (EHR) systems and EHR vendors to ensure EHR interoperability with public health information systems.	CDC, FDA, USDA, PHLs, Healthcare providers	Create new public health reporting objective for Meaningful Use Stage 3 to lay the ground work for public health population data reporting in the future	PHRI involves participation from 30+ users across 5 domains.	2011-present	Merrick interview	PHRI is not currently tackling immunizations or aggregate data.