June 2001

Food Testing Laboratory Industry Database

Final Report

Prepared for

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1 Introduction

Private laboratories play an important and growing role in helping the Food and Drug Administration (FDA) ensure that imported food products are not in violation of the Food, Drug, and Cosmetic Act. The volume of imported foods has grown rapidly in recent years and is expected to continue to grow rapidly. Due to this growth, the FDA relies on private laboratory tests of imported foods to determine whether the foods should be allowed to enter the United States. Private sector laboratories test regulated food products and submit data to FDA demonstrating compliance with the Act. These laboratories are not owned by the firms that utilize their services and are defined as independent providers of services. As the volume of imported foods increases, it is important for the Agency to have information on the laboratories performing analyses.

The FDA also relies on private laboratory data to evaluate the compliance of seafood processors with the Hazard Analysis and Critical Control Point (HACCP) regulations, which require some analytical testing of hazardous raw materials. In addition to their use in current programs, the use of private laboratories may increase in the future as the Agency promulgates new food safety programs with provisions for testing. The FDA requires information on the size, testing capabilities, and other activities of the laboratories that provide test results.

1.1 STUDY OBJECTIVES

In September 2000, FDA contracted with Research Triangle Institute (RTI) to collect information about the characteristics and

capabilities of the private laboratories that submit test packages to the FDA and to prepare a database containing this information. The primary objective of this study is to provide FDA with information that can be used to assess the quality and uniformity of results reported by private laboratories. For the purposes of this study, we used FDA's (1997) definition of private laboratories. We included private laboratories that perform analyses on regulated food products and that may submit analytical data to FDA to demonstrate compliance with the Food, Drug, and Cosmetic Act. Private laboratories were defined as independent providers of services that are not owned by the firms that utilize those services.

Data on private laboratories were collected from FDA sources (e.g., Operational and Administrative System for Import Support [OASIS]) and publicly available sources on the range of companies that offer food testing services in the United States and a survey of food testing laboratories in other countries. This information was then compiled into a database that documents laboratory location, contact information, economic variables, test capabilities, and quality assurance programs (QAPs).

1.2 OVERVIEW OF THE FOOD TESTING LABORATORY DATABASE

The Food Testing Laboratory Database (FTLD) is a Microsoft Access database that contains 546 records of companies that test food. It includes the variables needed to support the kinds of analyses FDA expects to undertake—such as location and contact information, economic variables, test capabilities, and QAPs—and allows FDA to add more data in the future. The FTLD allows users to

- ➤ sort laboratories by location (e.g., state or country),
- ➤ query laboratories owned by one parent company,
- ➤ sort laboratories by capabilities,
- ➤ sort laboratories that use QA guidelines such as International Organization for Standardization (ISO) standards, and
- ➤ determine laboratories associated with a certain geographic area or FDA district.

In addition to these basic capabilities, RTI has conducted a preliminary analysis and review of the QAP status of the food

testing laboratories. This analysis is limited because the extent of implementation of the QAP indicators used in the FTLD was unclear based on the availability and nature of the secondary sources. We describe four suggestions for supplementing FTLD and related analyses including recommendations that will assist FDA in describing the QAP status of private food testing laboratories.

1.3 OVERVIEW OF THE REPORT

This report is organized as follows. Section 2 describes the selection process used to distinguish food laboratories from other laboratories and the sources from which we drew the data. Section 3 describes the structure of the FTLD, including the variables, tables, and forms that make up the database. It also describes how we defined the testing capabilities. Section 4 summarizes our preliminary analysis of the QAP status of private food testing laboratories and presents recommendations for further research.

2 Laboratory Selection

RTI compiled the list of private laboratories using a variety of secondary sources. Using laboratory Standard Industrial Classification (SIC) codes, RTI purchased a list of testing laboratories from *infoUSA*. Laboratories that perform only nonfood tests or that otherwise did not meet the definition of private laboratories were excluded from this preliminary list. The exceptions to these guidelines were multi and international laboratories. Although laboratories outside the United States are excluded from regulatory jurisdiction, many foreign labs have submitted data to demonstrate compliance of imported food products or advertise food testing capabilities and were therefore included in the database.

2.1 DATA SOURCES

RTI purchased data from *infoUSA* both to identify potential laboratories to include in the FTLD and to obtain demographic information for testing laboratories. RTI used several additional sources of information to identify laboratories that advertise or had confirmed food testing capabilities. If a laboratory web site contained information that differed from *infoUSA*, it was presumed that the web site was more current and therefore web site information was used. In addition to the sources listed below, RTI supplemented the database with information that we had collected on other projects. The information source is documented in the source column on the Laboratory Information Form and accounts for reasons of inclusion in the database. Following is a brief list of primary sources used, with abbreviations noted in parentheses.

Accredited Laboratory Program (ALP)—Laboratories accredited by the U.S. Department of Agriculture's (USDA's) Accredited Laboratory Program.

American Society of Testing and Materials (ASTM)—Company directory.

Operational and Administrative System for Import Support (OASIS)—And other OASIS-related materials received from FDA. Also includes sites with affiliations to the confirmed OASIS laboratory.

Web Sites (Web)—Mostly web sites for laboratories and companies. Occasionally, a laboratory without a company web site was referenced on university extension, HAACP, or trade association sites and was noted accordingly.

Food Quality Buyers' Guide (FQBG)—Guide to products, services, and company directory that is published as a supplement to *Food Quality Magazine*.

Institute of Food Technologists' (IFT)—Membership directory and/or classified advertisements from IFT trade magazine.

Honey Board List of Food Testing Laboratories (HB)—Producer-funded organization that provides laboratory references and information.

American Spice Trade Association Certified Lab List (ASTA)—American Spice Trade Association is an organization that promotes trade of spices and offers a list of approved testing laboratories.

2.2 DEFINING THE LABORATORY POPULATION

The food testing industry is not well defined. Therefore, the list of laboratories that we compiled include those that market directly to the food industry, laboratories that are not food related (e.g., medical, construction, environmental), and companies that seemingly have no relation to the testing industry at all (e.g., Artco Picture Frames, Tupperware Home Parties, American Labor, Inc.). It is worth noting that many of the non-laboratory references were retrieved from OASIS. In addition, because our research methodology relied on information available from the World Wide Web and from professional organizations, it is possible that certain

laboratories without web sites or memberships to professional organizations were omitted during this process.

2.2.1 Sorting Purchased Data

The initial list of laboratories purchased from *infoUSA* included over 5,000 testing and calibration laboratories that are included in SIC code 8734-02, which pertains to laboratories providing testing services. Laboratories that do not test food products were initially excluded from this list as described below.

The remaining laboratories were grouped into categories based on name, and 5 to 10 examples from each category were reviewed. Some laboratory categories required closer scrutiny, such as "Analytical," "Agri," "Testing," and laboratories with "food" in their name. Based on our review, we omitted the following types of laboratories:

- Agri
- Aqua
- BioAssay
- Calibration
- Clinical/Drug Testing
- Construction
- Engineering/Inspection
- Environmental
- Geo
- Hemo
- Laboratory Equipment/Test Kit Manufacturers
- Mammography
- Medical/Diagnostic
- Metallurgical
- Plastic/Polymer
- Scientific Suppliers and Warehouses
- Technology/Computer
- Terra
- Testing
- Water

Clearly, some of these laboratories may have food testing capabilities and may test food occasionally. For example, laboratories that test water for coliforms might also test food samples for microbiological contaminants. Also, many of the Agri laboratories that we reviewed tested cattle feed that may indirectly contribute to the human food supply. If a laboratory fell into one of these categories but was referenced by a corroborating source, it was included in the FTLD. An example of this would be Professional Service Industries, Inc.—the company's web site indicated construction services but the company was listed in ACIL as having food testing capabilities and was therefore included in the database.

2.2.2 Expert Review

As an additional source of information, we contacted food science personnel at six universities to review the list of companies that test food in their region of the country:

- Cornell
- North Carolina State University
- Penn State
- Texas A&M
- University of California, Davis
- Virginia Tech

The experts that we contacted generally agreed with the laboratories selected for inclusion. They also provided the names of about a dozen companies that test food but were not included on the list. Based on their suggestion, these companies were included in the FTLD.

3 Database Design and Use

The FTLD is a Microsoft Access database that opens to a switchboard window. From the switchboard, a user can

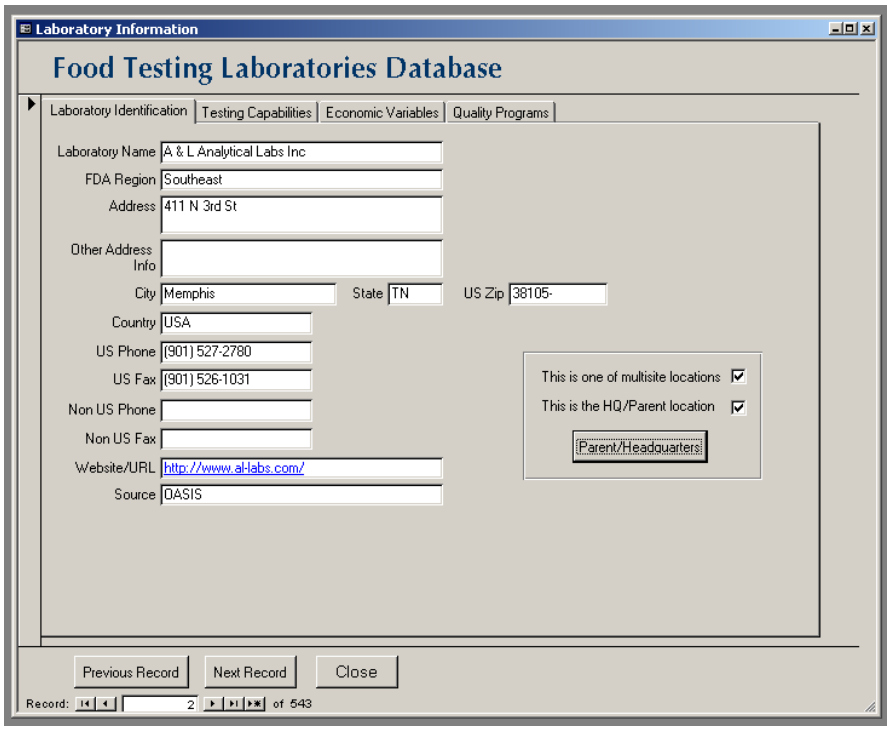
- ➤ view detailed information specific for each laboratory site,
- ➤ view quality program information,
- ➤ sort by test capabilities, or
- ➤ reach underlying tables.

This section discusses the layout of the database following the switchboard screen and then provides some short notes on use.

3.1 LABORATORY INFORMATION FORM

Figure 3-1 presents the Laboratory Information Form that was created as the main user interface for the FTLD. The laboratory view uses tabs to order the flow logically, visually divide the information, and group related types of information. The Laboratory Information Form contains four tabs: Laboratory Identification, Testing Capabilities, Economic Variables, and Quality Programs. This form also contains a subsection that indicates whether the laboratory is a multi or headquarters site. A button link is provided to Parent/Headquarters details when available (see Figure 3-1). This section discusses the information for each tab on the Laboratory Information Form.

Figure 3-1. Example Laboratory Information View with Four Tabs



3.1.1 Laboratory Identification Tab

The Laboratory Identification Tab (Lab ID Tab) contains the variables listed in Table 3-1. In addition, information is available on this page that indicates whether the laboratory is a multi or headquarters location and connects to laboratory parent information when available. Multisite indicates that reference was made to other laboratory locations, although the reference may or may not have provided details regarding a headquarters site. When general reference was made to many locations, lack of detail and specificity prevented inclusion in FTLD. Clicking the *Parent/Headquarters* button accesses information about the parent company or headquarters address for each laboratory location (Figure 3-2). Parent information was obtained during secondary information collection.

Table 3-1. Variable Descriptions

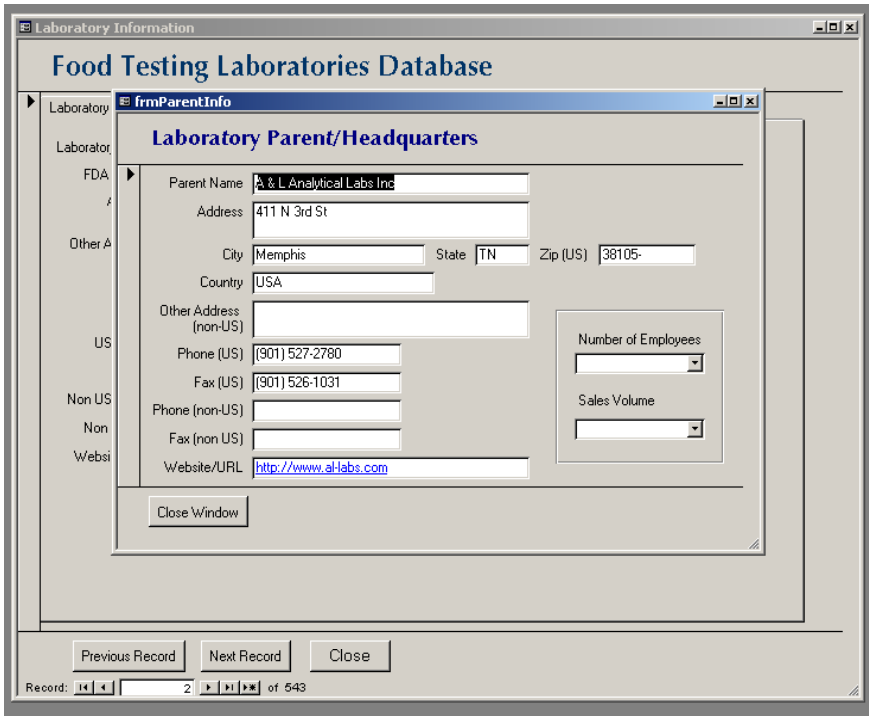
Variable Name	Format	Description
		Laboratory Identification
Laboratory Name	Text	Facility name
FDA Region	Text	Linked to FDA Region table—compiled from FDA site <www.fda.gov/ora/Partnership_Agreements/contracts/current.html>
Address	Text	Street address
Other Address Info	Text	Additional postal information
City	Text	City
State	Text	State
Zip Code	Number	Zip code (5 digits)
Country	Text	Specifies location if in a foreign country
Phone (US)	Number	Phone number
Fax (US)	Number	Fax number
Non US Phone	Number	Foreign phone information
Non US Fax	Number	Foreign fax information
Web Site/URL	Link	Internet address
Source Record	Text	Documents the reason that this laboratory was included in the database
		Parent or Headquarters Information
Parent Name	Text	Name of the parent that owns laboratory or headquarters
Parent Address	Text	Street address of parent company or headquarters
Parent City	Text	City location of parent company or headquarters
Parent State	Text	State of parent company or headquarters
Parent Zip	Number	Zip code (5 digits) of parent company or headquarters
Parent Country	Text	Specifies parent location if in a foreign country
Other Address (Non US)	Text	Additional location information
Parent Phone (US)	Text	Phone number of parent company or headquarters
Parent Fax (US)	Text	Fax number of parent company or headquarters
Parent Phone (Non US)	Text	Parent phone if outside of United States
Parent Fax (Non US)	Text	Parent fax if outside of United States
Web Site/URL	Text	Parent web site link
Number of Employees	Text	Number of employees within company
Sales Volume	Text	Range of company profit (in thousands)

(continued)

Table 3-1. Variable Descriptions (continued)

Variable Name	Format	Description
		Information on Economic Variables
Laboratory Name	Text	
Year Established	Number	Year of establishment
Number of Employees	Text	Approximate number of employees at site
Sales Volume	Number	Sales range (in thousands)
Primary SIC	Number	Standard Industrial Classifications
Primary NAICS	Number	North American Industry Classification System
Name	Text	Primary laboratory contact
Phone (US)	Number	Contact phone
Phone (Non-US)	Number	Contact phone if outside United States

Figure 3-2. Example Parent Information



3.1.2 Testing Capabilities Tab

An important aspect of the FTLD is the testing capabilities for each laboratory. RTI designated a specific list of testing attributes and characteristics to include in the database. A broad definition for chemical and microbiological testing was needed for laboratories that did not itemize specific tests. Also, many test methods are closely related (e.g., proximate analysis/nutritional content) and can fall into multiple categories. These methods therefore required judgment on the part of data preparation personnel. Using the secondary resources cited above, information was gathered on the testing capabilities outlined in Table 3-2. The *View Testing Capabilities by Category* button (Figure 3-3) provides the user with a quick assessment of the types of tests performed by the laboratory (e.g., microbiological, water).

3.1.3 Economic Variables Tab

The Economic Variables tab is shown in Figure 3-4. The initial *infoUSA* data included basic laboratory economic information, such as the year of laboratory establishment, number of employees, and sales volume. As laboratory web sites are maintained primarily for promotional purposes and association sources do not include economic variables, it was our experience that sales volume information was not readily available and not easily confirmed.

3.1.4 Quality Programs Tab

The Quality Programs tab (Figure 3-5) includes laboratory name and a list of QAP indicators that provide a sample of information on three types of QAPs: national programs, trade association-sponsored programs, and ISO-related programs. Each QAP indicator included in the database is briefly described in Section 3.2.

3.2 VIEW QUALITY PROGRAM INFORMATION

The View Quality Program Information button is available from the main switchboard and provides access to detailed information on both national and international QAPs (Figure 3-6). These QAP indicators are assigned into four categories: oversight programs,

Table 3-2. Guide for Testing Capabilities

If the laboratory tests for or performs tests that include...	Then this category applies:
Antibiotics or inhibitors, sulfa drugs, tetracycline, beta lactams, penicillin	Antibiotics and/or inhibitors
Fats, oils, cholesterol, peroxide value, saponification, rancidity, etc.	Fats and oils
Flavoring and/or spice	Flavorings and/or spices
Chemical testing (general or not specified)	General chemical testing
Nickel, zinc, total chromium, lead	Metals
Aluminum, arsenic, calcium, iodine, and phosporous, etc.	Minerals
Nutritional content for labeling	Nutrient content
Pesticide residues	Pesticide residues
Preservatives, additives, and colors	Preservatives, additives, and colors
Proximate analysis, moisture, protein, fat, salt	Proximate analysis
Vitamins A, B, C, K, thiamin, ascorbic acid, etc.	Vitamins
Campylobacter spp	*Campylobacter* spp
Coliform/total or fecal coliform/*E. coli*/*E. coli* 0157:H7	Coliform
Microbiological testing (general or not specified)	General microbiological testing
Listeria spp, environmental swabs	*Listeria* spp
Microbial identification by API, biochemical testing, phage typing, and other identification means	Microbial identification
Microbial (general or not specified)	Other microbes
Salmonella spp	*Salmonella* spp
Staphlycoccus spp	Staphlycoccus spp
Vibrio spp	*Vibrio* spp
Bioengineering, genetic modifications, genetic-based microbial detection, genetic sequencing	Biotechnology
Spoilage, off-odors, off-colors, filth, microscopy, extraneous matter, foreign material/ objects	Decomposition and filth
Nonspecies adulteration (e.g., water in milk), sweeteners, ingredient and label reviews	Other adulteration
Species check for meat, fish	Species adulteration
Toxicological	Toxicology
Specified HACCP	HACCP
Specified imported foods	Imported foods
Listed in Operational and Administrative System for Import Support	OASIS
Histamine	Histamine
Aflatoxin, other mycotoxin	Mycotoxin
S. Aureus toxin, endotoxin, etc.	Other natural toxins
Toxins (general or not specified)	Toxins
Specified drinking water	Drinking water
Water (general or not specified)	General water
Specified waste water	Waste water

Figure 3-3. Example Testing Capabilities Tab

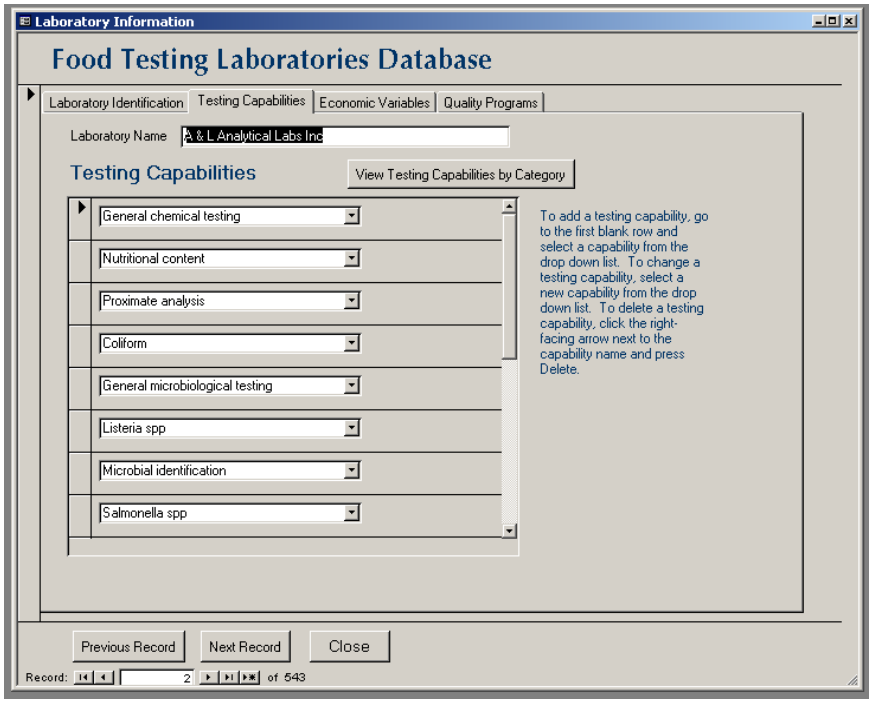


Figure 3-4. Example Economic Variables Tab

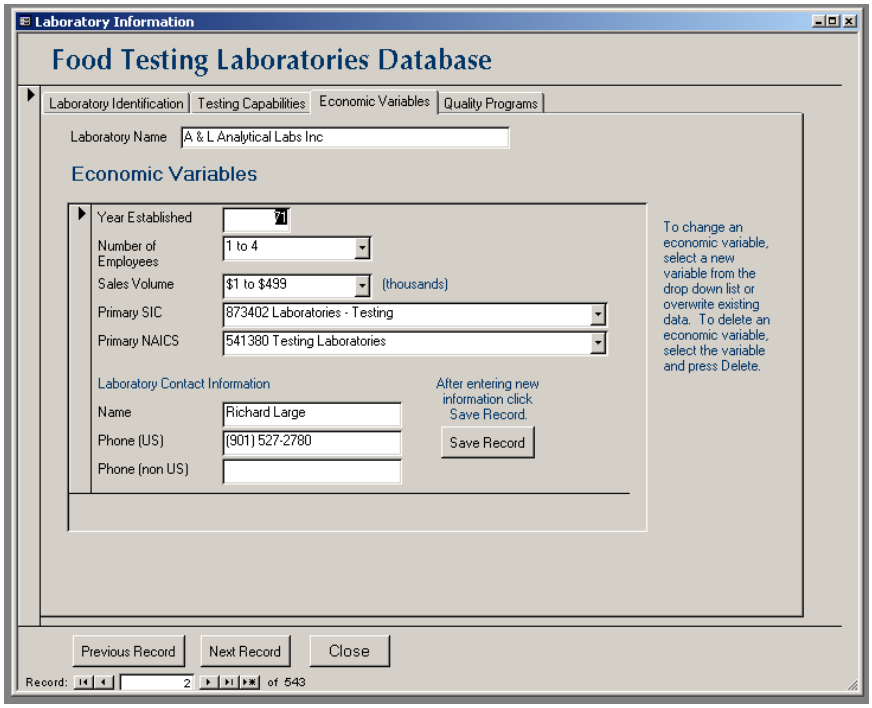


Figure 3-5. Example Quality Programs Tab

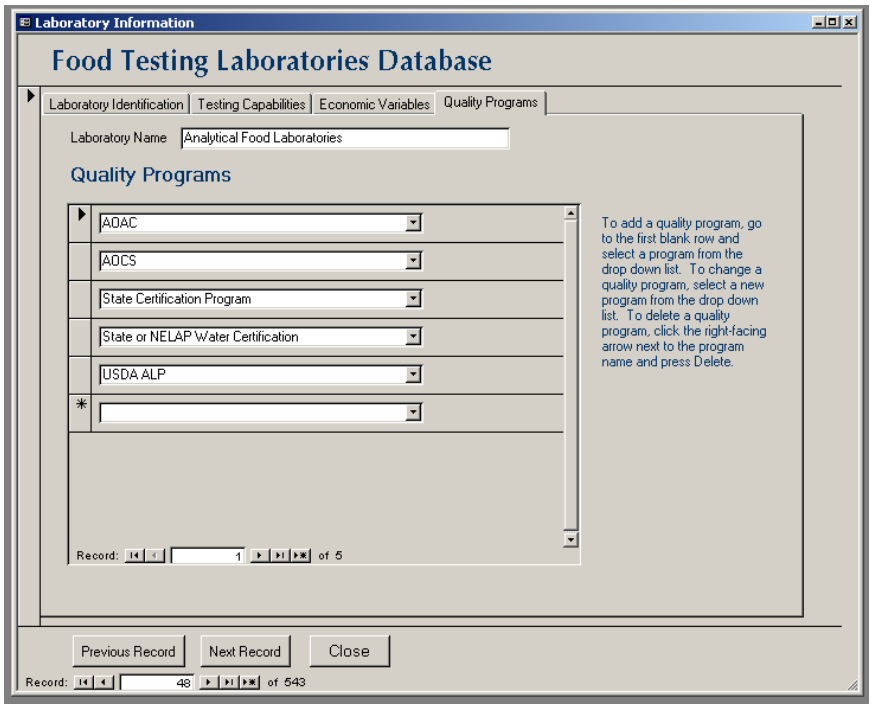
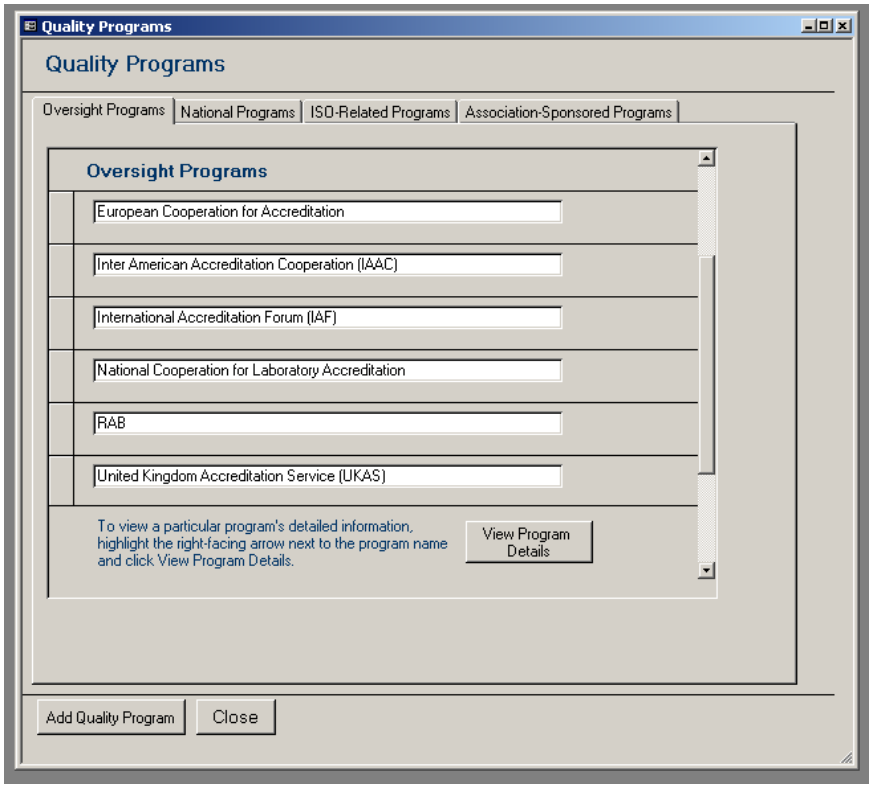


Figure 3-6. Example Oversight Programs Tab



national programs, ISO-related programs, and association-sponsored programs.

3.2.1 Oversight Programs

Oversight programs are national and international programs that assure uniform standards of execution for quality programs (e.g., American National Standards Institute [ANSI] and Registrar Accreditation Board [RAB]). Oversight may include proficiency and accreditation. The *View Program Details* button provides location and contact details for each program.

3.2.2 National Programs

Nationally- and state-sponsored programs are important QAP indicators of laboratory quality. For this reason, we have included brief descriptions of the programs used as QAP indicators.

Accredited Laboratory Program (ALP)—USDA offers voluntary accreditation to nonfederal, analytical chemistry laboratories that analyze meat and poultry foods for moisture, protein, fat, salt (MPFS), and chemical residues. ALP accreditation is limited to meat and poultry, and an accredited laboratory may be used in lieu of an FSIS laboratory to analyze official regulatory samples. Accreditation is based on quarterly proficiency testing.

Good Laboratory Practices (GLPs)—EPA and FDA regulations that mandate quality practices for premarket approval studies of drugs, pesticides, and food additives. Participating facilities are subject to periodic or directed inspections. The U.S. GLPs are internationally recognized, for example in a Memorandum of Understanding (MOU) with Japan. Also, the Organization for Economic Cooperation and Development (OECD) offers similar standards that are internationally recognized.

Good Manufacturing Practices (GMPs)—FDA regulations that require QA practices for drug manufacturing facilities. Many laboratories manufacture drugs on a small scale or perform testing to support regulated facilities and are therefore regulated. For instance, one laboratory at RTI manufactures drugs as part of the accreditation program for drug testing laboratories so RTI is an FDA-registered GMP facility. All regulated facilities are subject to inspection by FDA.

National Environmental Laboratory Accreditation Program (NELAP) or State Water Accreditation—NELAP accrediting authorities review testing for environmental legislation including the Clean Air Act; Clean Water Act; Resource, Conservation and Recovery Act; Safe Drinking Water Act; and the Comprehensive Environmental Response, Compensation, and Liability Act. Many states are official accrediting authorities recognized by NELAP. Other states have similar programs but are not recognized by NELAP or at least have a drinking water and/or wastewater certification program. We noted NELAP certification and similar state certification programs in the database as a preliminary indication of laboratories that test water.

USDA-Recognized Laboratory for Pasteurized Egg Products—USDA offers recognition for participation in a proficiency-testing program for samples of pasteurized egg products such as powdered and liquid egg products.

USDA Recognized—Many labs indicated recognition by a USDA program that was not disclosed, or some labs stated recognition by a USDA program that was not used as a QAP indicator.

Other Regulatory or Quality Program—Any other regulatory mandated or prescribed QAP conducted at the national level. Labs in the United States frequently listed the FDA Shellfish Sanitation Program, and labs in other countries may use a program prescribed by that country's regulating body.

State Certification—Provides general information that a company uses a state certification program that was not described or categorized.

3.2.3 Trade Association-Sponsored Programs

Large industry and trade associations offer quality programs such as proficiency testing and certified laboratory or analyst, and these were used as QAP indicators. Association programs that were frequently cited in secondary sources have been included in the database and are listed below.

AOAC International (AOAC)—Offers proficiency-testing programs that focus on laboratory analysis of food products. Programs include pesticide residues in fruits and vegetables, standard microbiology, pathogen-free microbiology, pathogens in meat, nutritional labeling, and HAACP. The AOAC proficiency-testing program for food analysis is currently the only food analysis program accredited by A2LA.

American Association of Cereal Chemists (AACC)—Offers several check sample or proficiency-testing programs for several tests at various intervals. For example, AACC offers quarterly microbiological samples and bimonthly samples for sodium, vitamins, and proximate analysis. Sample types include grains, spices, feed, cereal, and flour and bakery products.

American Association of Feed Control Officials (AAFCO)—The AAFCO Feed Check Sample Program consists of 12 samples each year that include a variety of feeds and supplements with drugs, antibiotics, minerals, and vitamins at levels normally encountered in commercial products.

American Oil Chemists' Society (AOCS)—According to the AOCS web site, the AOCS offers the most extensive collaborative check sample program for oil- and fat-related commodities, oilseed meals, and edible fats. Sample types include seed, fish and corn meals, soybeans, oils, fats, tallow, grease, peanut butter, and milk. Tests include nutritional labeling, moisture, nitrogen, free fatty acids, oil, ash, color, iodine, peroxide, melting point, feed microscopy, aflatoxin, and others. AOCS recently initiated a GMO check sample program that requires documentation on the method used rather than requiring that an analysis be conducted using a standard method. In addition to the check sample programs, AOCS offers a certified laboratory program called the Laboratory Proficiency Program (LPP) and an analyst certification called the Approved Chemists Program.

Other Proficiency Programs—Indicates the use of QAPs that are not explicitly listed in the FTLD.

3.2.4 ISO-Related Programs

The ISO was used as a QAP indicator. The ISO is a non-governmental organization established in 1947 and is a worldwide

federation of national standard bodies from 130 countries (one from each country). When an industry sector recognizes the need for standardization, it communicates that need to the national member body, which then presents it to ISO for definition of technical scope. International standardization is market-driven and based on voluntary involvement of the marketplace. ANSI is the U.S. representative to the ISO, although it is worth noting that many organizations promote adherence to ISO guidelines (e.g., ACIL, NVLAP, A2LA, etc). For the purpose of the FTLD, we selected the ISO box if the lab indicated that it adhered to any ISO standard (including 17025).

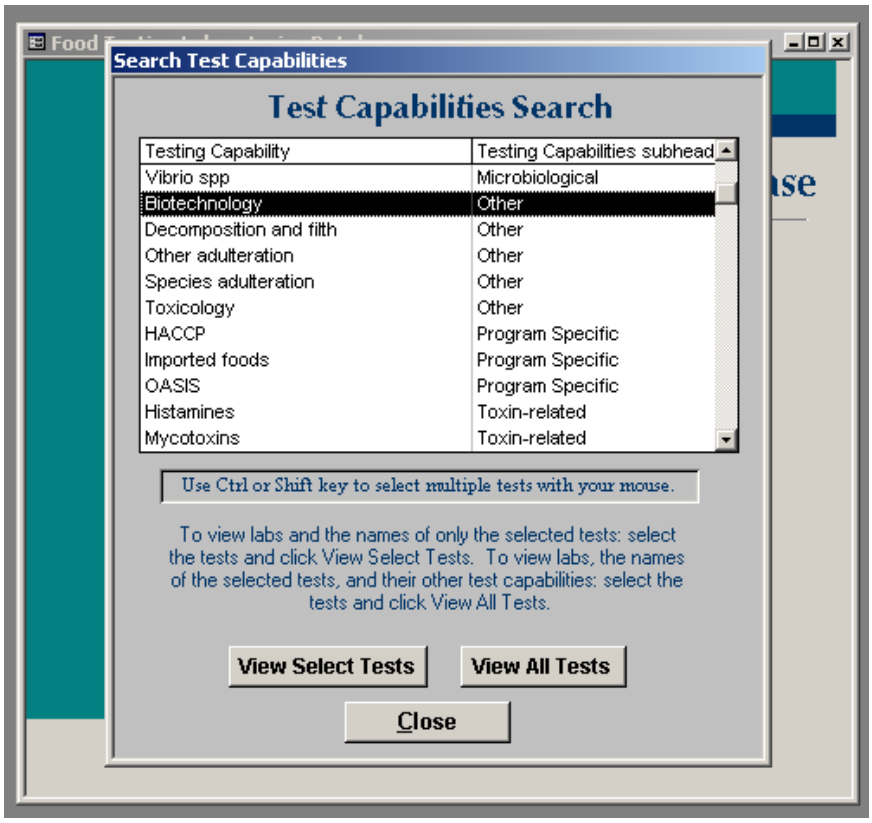
ISO—The ISO 9000 series is a series of general quality assurance and quality management standards set by the ISO. In addition to the ISO 9000 series, the ISO category in the FTLD includes general references to ISO and references to ISO standards other than 17025.

ISO 17025—The ISO 17025 standard is specific to laboratory testing and is based on ISO 9000 with added requirements for technical competence for laboratories. This new standard, published in January 2000, was formerly published as ISO Guide 25. In the course of our laboratory research, we realized that many of these membership organizations are still in the process of rolling over from the guidance to the standard. Labs accredited by A2LA scheduled to comply with 17025 by July 2001 were represented as complying with the ISO 17025 standard in the FTLD. We also selected 17025 for other labs that indicated adherence to these standards.

3.3 SEARCH TEST CAPABILITIES

From the main switchboard, a listing of test capabilities is provided (Figure 3-7). This feature allows the user to quickly determine which laboratories are capable of performing a specific test (e.g., biotechnology). After highlighting the specific test(s) required, the *View Select Tests* button will access an established query that lists laboratories with that capability. An example of this would be a query of laboratories that provide biotechnology testing.

Figure 3-7. Example Test Capabilities Search



3.4 USING THE DATABASE

The database incorporates various tools for navigating, editing, and searching. Using the F11 key from the main switchboard provides access to the tables used in building the database. You must be in "tblLabIdentification" to add or delete a laboratory. Certain measures are in place to assure that information is not inadvertently amended. It is necessary to be in the table to edit location or contact information; that function cannot be performed directly from the form view.

To quickly filter information, highlight the desired field and right click on the mouse; filter options will appear. Using the keyboard Tab key will quickly move the user from field to field throughout the database.

4 Conclusions

Since FDA relies on private laboratory submissions to monitor food safety, it is important to have quality control information for these labs. Although laboratories are not required to participate in QAPs in order to submit food safety data, many labs voluntarily use QAPs such as proficiency testing or certification programs. RTI totaled the QAP indicators in the database as an initial assessment of the QAP status of the food testing industry. However, this preliminary estimate is limited because the extent of implementation of the QAP indicators used in the FTLD was unclear based on the availability and nature of the secondary sources.

4.1 SOURCE LIMITATIONS

Two main limitations of secondary source data collection became clear as the FTLD was being developed: limited availability of secondary sources and information gaps within a source. Regarding the first limitation, we were unable to locate a secondary source for certain companies. We expect that many of the companies without web sites may be small businesses. Based on discussion with ACIL, their membership consists mostly of large laboratories. Many small laboratories cannot afford the cost of membership to ACIL. Most likely, many of these companies cannot afford to participate in QAPs.

Regarding the second limitation, much of the secondary information that was available was promotional and did not contain the fields of information presented in the FTLD. Companies typically did not discuss information such as SIC code or revenues. Test capabilities and QAPs presented by the companies were frequently generalized.

4.2 PRELIMINARY ESTIMATE OF QAP PARTICIPATION

Table 4-1 provides a preliminary estimate of participation in QAPs. This preliminary estimate is limited because the extent of QAP implementation was unclear in the secondary sources. Three factors regarding the extent of implementation were unclear:

- ➤ the location of certification,
- ➤ the extent of certification, and
- ➤ the level of compliance.

Table 4-1. Preliminary Estimate of Participation in QAPs

QA Program	Count
AACC	48
AAFCO	12
AOAC	47
AOCS	49
FDA GMPs	54
FDA/EPA GLPs	41
ISO	66
ISO 17025	46
Other Proficiency Program	14
Other Regulatory or Quality Program	33
State Certification Program	56
State or NELAP Water Certification	85
USDA ALP	54
USDA Pasteurized Egg Products	16
USDA Recognized	22

Much of the information available from secondary sources characterizes the company rather than an individual location, which makes it difficult to determine actual locations that are certified. For example, Woodson-Tenent's web site listed AOCS certification but did not specify that 4 sites of approximately 13 laboratories owned by Woodson-Tenent are certified by AOCS (AOCS, 2001). Similarly, companies state that USDA accredits them if they are accredited at one site. For labs with many locations, this may mean a high number of QAPs listed incorrectly in the preliminary analysis when detailed information was unavailable (see Table 4-1).

Another area that requires clarification is the certification coverage. Some companies say that they are certified and do not specify what part of the organization is certified. For example, a company may be certified to ISO 9000, but the certification may include only certain divisions and not include the laboratory.

The level of QAP compliance was typically not discernable from the secondary sources. The coverage and level of implementation affects the strength of the QA systems and monitoring. The preliminary assessment of FTLD indicates 41 laboratories that claimed GLP; however, the level of GLP involvement was unclear (see Table 4-1). These labs may be GLP-regulated or may work "in the spirit of GLPs." Work done in the spirit of GLPs has no binding stipulations. In contrast, GLP-regulated labs are subject to federal inspections on regulated studies, and facilities used in these studies operate with an independent QA unit. Similarly with ISO standards, a company may adhere to the standards without any binding constraints or may comply by various degrees of certification.

4.3 FURTHER RESEARCH

We describe four potential avenues for supplementing FTLD and related analyses including avenues that may help the Agency characterize the QAP status of private food testing laboratories. One of these suggestions or another option may be appropriate depending on the Agency's research direction.

- ➤ Develop a QAP profile that characterizes the program and participants, discusses implementation options, and estimates associated costs.
- ➤ Expand the database, for instance to include water testing companies including those accredited to the NELAP and water testing labs listed in *infoUSA*.
- ➤ Update the database for areas of rapid growth such as the GMO industry.
- ➤ Conduct case studies that characterize the extent and level of QAP implementation.

We will discuss with FDA the merits of posting the FTLD either on RTI's or FDA's web site to permit the public to view the database. A web mail mechanism might also be provided to enable the public

to send RTI or FDA comments on the accuracy and completeness of the FTLD. RTI or FDA could then update the FTLD as appropriate.

References

AOCS. AOCS Certification Programs List of 2000-2001 AOCS Certified Laboratories. <http://www.aocs.org/tech.labs.htm>. As obtained June 11, 2001.

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